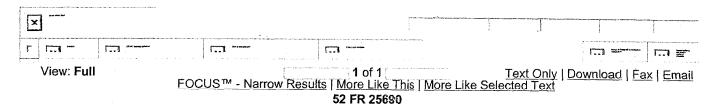
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Service: LEXSEE® Citation: 52 FR 25690

52 FR 25690

ENVIRONMENTAL PROTECTION AGENCY

AGENCY: Environmental Protection Agency (EPA).

40 CFR Parts 141 and 142

National Primary Drinking Water Regulations; Synthetic Organic Chemicals; Monitoring for Unregulated Contaminants

[WH-FRL-3213-8]

52 FR 25690

CLW

July 8, 1987

0000001586

ACTION: Final Rule.

SUMMARY: In this notice, EPA is promulgating National Primary Drinking Water Regulations (NPDWRs) for certain volatile synthetic organic chemicals (VOCs). Specifically, this notice promulgates maximum contaminant levels (MCLs) for: Trichloroethylene, carbon tetrachloride, 1,1,1-trichloroethane, vinyl chloride, 1,2-dichloroethane, benzene, 1,1-dichloroethylene, and para-dichlorobenzene. The NPDWRs also include monitoring, reporting and public notification requirements for these eight VOCs. EPA is also publishing the maximum contaminant level goal (MCLG) for para-dichlorobenzene. This notice specifies the best available technology (BAT) upon which the MCLs are based and BAT for the purpose of issuing variances. In this notice, the Agency is also promulgating procedures by which systems may obtain variances and exemptions from these NPDWRs. In addition to the NPDWRs for the eight VOCs, the Agency is also promulgating monitoring requirements for 51 other synthetic organic chemicals which are not regulated by NPDWRs.

EPA proposed NPDWRs, including MCLs, for the eight VOCs listed above on November 13, 1985 (50 FR 46902). New data on the toxicology of para-dichlorobenzene became available after the November 13 notice which changed its health effects classification. EPA proposed to amend the MCLG and reproposed the MCL for this contaminant on April 17, 1987 (52 FR 12876), based on this new information.

EFFECTIVE DATES: This regulation is effective January 9, 1989, except for §§ 141.24(g), 141.35, and 141.40. The information collection requirements in 40 CFR 141.24(g), 141.35, and 141.40 are effective January 1, 1988, if the information collection request is clear by the Office of Management and Budget (OMB) and an OMB clearance number is assigned prior to that date. If not, the requirements will be effective when OMB clears the request and a notice is published. In accordance with 40 CFR 23.7, this regulation shall be considered final agency

action for the purposes of judicial review at 1:00 pm eastern daylight savings time on July 22, 1987.

ADDRESSES: Public comments on the proposal, major supporting documents, and a copy of the index to the public docket for this rulemaking are available for review during normal business hours at the EPA, Room 2904 (rear) in the Public Information Reference Unit, 401 M Street, SW., Washington, DC 20460. A complete copy of the public docket is available for inspection at EPA in Washington, DC by appointment by contacting Ms. Colleen Campbell 202/382-3027.

FOR FURTHER INFORMATION CONTACT: Joseph A. Cotruvo, Ph.D., Director, Criteria and Standards Division, Office of Drinking Water (WH-550), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, 202/382-7575, or one of the EPA Regional Office contacts listed in "Supplementry Information". Information may also be obtained from the EPA Drinking Water Hotline. The toll-free number is 800/426-4791 and the Washington, DC number is 382-5533.

TEXT:

SUPPLEMENTARY INFORMATION:

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Abbreviations Used in This Notice

BAT: Best Available Technology

BTGA: Best Technology Generally Available

CWS: Community Water System

EMSL: EPA Environmental Monitoring and Support Laboratory (Cincinnati)

GAC: Granular Activated Carbon

CLW

LOQ: Limit of Quantitation

MCL: Maximum Contaminant Level (expressed as mg/1) *

MCLG: Maximum Contaminant Level Goal

MDL: Method Detection Limit

mgd: Million Gallons per Day

NIPDWR: National Interim Primary Drinking Water Regulation

NPDWR: National Primary Drinking Water Regulation

NTNCWS: Non-transient Non-community Water System

p-dcb: para-Dichlorobenzene

POE: Point-of-Entry Technologies

POU: Point-of-Use Technologies

PQL: Practical Quantitation Level

PTA: Packed Tower Aeration

PWS: Public Water System

PWSS: Public Water System Supervision

RMCL: Recommended Maximum Contaminant Level

SDWA: Safe Drinking Water Act, or the "Act," as amended in 1986

THMs: Trihalomethanes

URTH: Unreasonable Risk to Health

VOC: Volatile Synthetic Organic Chemical

* 1,000 micrograms (ug) = 1 milligram (mg)

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I. Summary of Today's Action

Applicability

The requirements of this notice apply to all community water systems (CWS) and montransient non-community water systems (NTNCWS).

Non-transient non-community water systems are those which regularly serve the same 25 or more persons at least 6 months per year.

Final MCLG:

para-dichlorobenzene -- 0.075 mg/l

Final MCLs:

- 1. benzene -- 0.005 mg/l
- 2. carbon tetrachloride -- 0.005 mg/l
- 3. 1, 2-dichloroethane -- 0.005 mg/l
- 4. trichloroethylene -- 0.005 mg/l
- 5. para-dichlorobenzene -- 0.075 mg/l
- 6. 1,1-dichloroethylene -- 0.007 mg/l
- 7. 1,1,1-trichloroethane -- 0.20 mg/l
- 8. vinyl chloride -- 0.002 mg/l

BAT under Section 1412 of the SDWA (MCLs):

Packed tower aeration (PTA) or granular activated carbon (GAC) for all regulated VOCs, except vinyl chloride.

PTA for vinyl chloride.

Other effective removal technologies that treat all of the drinking water in a public supply although not designated BAT may also be applied to achieve compliance.

BAT under Section 1415 (Variances):

Same technologies are BAT as those under Section 1412.

Monitoring Requirements and Compliance Determination

The basic monitoring requirements are as follows:

CLW

Quarterly samples for each ground and surface water source.

Composite samples of up to five sources are allowed.

Monitoring requirements are phased in by system size (i.e., population served)

Population served Monitoring must begin by

>10,000 Jan. 1, 1988. 3,300-10,000 Jan. 1, 1989. <3,300 Jan. 1, 1991

Determination of compliance is established as follows: Both ground and surface water systems must calculate a running average of the concentration of each VOC, over one year, taking at least one sample per quarter, for each source.

All samples must be used.

For ground waters, the State as primacy agent may reduce the sampling frequency if regulated VOCs are not detected in the first sample. The minimum possible monitoring requirement for compliance is one sample per source.

Repeat monitoring varies from quarterly to once per five years. States determine repeat monitoring requirements based on: (1) Whether or not VOCs have been detected in the initial sampling, and (2) the vulnerability of the system to contamination (determined by the State).

Analytical Methods:

- 1. EPA Method 502.1 -- Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography.
- 2. EPA Method 502.2 -- Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography with Photoionization and Electrolytic Conductors in Series.
- 3. EPA Method 503.1 -- Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography.
- 4. EPA Method 504 -- 1,2-Dibromoethane and 1,2-Dibromo-3-chloropropane in Water by Microextraction and Gas Chromatography.
- 5. EPA Method 524.1 -- Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography/Mass Spectrometry.
- 6. EPA Method 524.2 -- Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography/Mass Spectrometry.

Laboratory Certification Criteria

Vinyl Chloride:

+/- 40 percent at any concentration

All others:

+/- 20 percent >/= 0.010 mg/l

CLW 0000001591 +/- 40 percent < 0.010 mg/l

Point-of Entry Devices (POE), Point-of-Use Devices (POU), and Bottled Water

POE may be used to achieve compliance with MCLs; however, POE is not BAT.

POU and bottled water cannot be used to achieve compliance with the MCLs; however, either may, at State discretion, be a condition of granting a variance or exemption.

Variances and Exemptions

Prior to issuing a variance or exemption, the State has the authority to require the public water system to implement additional interim control measures if an unreasonable risk to health exists; among other mitigation techniques, States may require installation of point-of-use devices or distribution of bottled water to each customer as measures to reduce the health risk before granting a variance or exemption.

Monitoring for Unregulated Contaminants

One sample per source is required every five years.

Systems sample according to the procedures and schedules established for VOC compliance monitoring.

Monitoring for the 50 unregulated contaminants is as specified below:

List 1: monitoring required for all systems (34 contaminants).

List 2: monitoring required for vulnerable systems (2 contaminants).

List 3: monitoring required at State discretion (15 contaminants).

Repeat monitoring frequency: Every five years.

EPA will specify a new list before repeat monitoring is required (within five years).

II. Background

A. Statutory Authority

Section 1412 of the Safe Drinking Water Act, as amended in 1986 ("SDWA" or "the Act"), requires EPA to publish Maximum Contaminant Level Goals (MCLGs) and promulgate National Primary Drinking Water Regulations (NPDWRs) for contaminants in drinking water which may cause any adverse effect on the health of persons and which are known or anticipated to occur in public water systems. Under Section 1401, the NPDWRs are to include Maximum Contaminant Levels (MCLs) and "criteria and procedures to assure a supply of drinking water which dependably complies" with such MCLs. Under Section 1412(b)(7)(A), if it is not economically or technically feasible to ascertain the level of a contaminant in drinking water, EPA may require the use of a treatment technique instead of an MCL.

1. MCLs, MCLGs, and BAT

EPA is to establish MCLGs at the level at which no known or anticipated adverse effects on the health of persons occur and which allow an adequate margin of safety. MCLGs are nonenforceable health goals. EPA published MCLGs, previously called Recommended 1.5 9 2 Maximum Contaminant Levels (RMCLs), for trichloroethylene, carbon tetrachloride, 1,1,1-trichloroethylene, vinyl chloride, 1,2-dichloroethane, benzene, 1,1-dichloroethylene, and para-

dichlorobenzene on November 13, 1985. The Agency reproposed the MCLG for p-DCB on April 17, 1987 (52 FR 12876), based on new health assessment data.

MCLs are enforceable standards which the Act directs EPA to set as close to the MCLGs as feasible. "Feasible" means feasible with the use of the best technology, treatment techniques, or other means which the Administrator finds available (taking cost into consideration) after examination for efficacy under field conditions and not solely under laboratory conditions. Also, the SDWA requires the Agency to identify the best available technology (BAT) which is feasible for meeting the MCL for each contaminant. NPDWRs are to be amended whenever changes in technology or other means permit greater protection of the health of persons, and the regulations are to be reviewed no less frequently than every three years.

2. Variances and Exemptions

Section 1415 authorizes the State (the term "State" is used in this Preamble to mean the State agency with primary enforcement responsibility for the public water supply system program, or "primacy," or EPA if the State does not have primacy) to issue variances from NPDWRs. The State may issue a variance if it determines that a system cannot comply with an MCL despite application of the best available technology (BAT). Under Section 1415, EPA must propose and promulgate its finding of the best technology, treatment techniques, or other means available for each contaminant (BAT), for purposes of Section 1415 variances, at the same time that it proposes and promulgates a maximum contaminant level for each such contaminant. EPA's finding of best technology, treatment techniques, or other means available for purposes of issuing variances may vary among systems, depending upon the number of persons served by the system or for other physical conditions related to engineering feasibility and costs of complying with MCLs, as considered appropriate by EPA. The State may not issue a variance where an unreasonable risk to health exists. When a State grants a variance, it must at the same time prescribe a schedule for (1) compliance with the NPDWR and (2) implementation of such additional control measures as the State may require.

Under section 1416(a), the State may exempt a public water system from any MCL or treatment technique requirement if it finds that (1) due to compelling factors (which may include economic factors), the system is unable to comply, (2) the system was in operation on the effective date of the MCL or treatment technique, or, for a newer system, that no reasonable alternative source of drinking water is available to that system, and (3) the exemption will not result in an unreasonable risk to health. Under section 1416(b), at the same time it grants an exemption, the State is to prescribe a compliance schedule and a schedule for implementation of any required interim control measures. For exemptions from a NPDWR promulgated after enactment of the SDWA amendments, such as the NPDWRs for the VOCs promulgated in this notice, the compliance date must be no later than 12 months after the date of issuance of the exemption. However, the State may extend the final compliance date for a period not to exceed three years after the date of issuance of the exemption if the public water system establishes that it is taking all reasonable steps to meet the standard once: (1) the system cannot meet the standard without capital improvements which cannot be completed within the period of such exemptions; (2) in the case of a system which needs financial assistance for the necessary improvements, the system has entered into an agreement to obtain such financial assistance; or (3) the system has entered into an enforceable agreement to become part of a regional public water system. For systems that serve 500 or fewer service connections and which need financial assistance to come into compliance, the State may renew the exemption for additional two-year periods if the system is taking all practicable steps to meet the requirements in the previous senten

3. Primacy.

Today's regulation is one of many which EPA will promulgate during the next vew years, as required by the 1986 Amendments. To retain primary enforcement responsibility ("primacy")

for the public water system supervision program, States must revise their programs to include regulations that are no less stringent than the Federal NPDWRs, as required by Section 1413 of the Act, EPA plans to amend the Public Water System Supervision (PWSS) Program Implementation regulations, 40 CFR Part 142, to set out the requirements for these program revisions. The amendments will be based on the recommendations of an EPA workgroup which is currently reviewing the issues associated with such requirements. However, since these VOC regulations, promulgated under the authority of Section 1412, go into effect 18 months from the date of this notice, States must begin to modify their programs immediately without waiting for the amendments to 40 CFR Part 142.

The 18-month interval derives from Section 1412(b)(10) of the SDWA which requires that all NPDWRs be in effect no later than 18 months after the promulgation date. EPA takes the position, therefore, that the Federal NPDWRs directly apply to public water systems regardless of whether a State with primacy has adopted the requirements. As such, EPA has some discretion in establishing when States adopt the NPDWRs promulgated in today's notice since the Federal regulations will apply to all systems, even in States with primacy that have not adopted equivalent requirements.

EPA wishes, however, to avoid States having "split" or "partial" primacy, i.e., authority to implement and enforce only part of the PWSS program, for more than a short time. As such, EPA expects primacy States, to the maximum extent possible, to adopt State requirements as stringent as those contained in this Federal regulation within 18 months. Splitting oversight responsibilities, however briefly, will confuse public water system owners and operators as they try to determine which State and Federal regulations apply to them. In addition, EPA implementation and enforcement of regulations that States with primacy have not yet adopted will be limited since the EPA Regional Offices are not currently set up, or funded, to implement a day-to-day operational program. EPA believes that States should operate the total PWSS program, including the changes contained in any new regulations, from the effective date onward.

As the monitoring requirements of this regulation go into effect sooner than eighteen months after publication i.e., January 1, 1988, States with primacy should inform systems under their jurisdiction of their responsibilities under Federal law and ensure that they are monitoring even though the State may not yet have its requirements in place. Further, States should collect and manage the analytical results during this interim period as though they had incorporated the program revisions. States should forward information on violations of the Federal requirements to the applicable EPA Regional Office.

As mentioned in the first paragraph of this section, EPA plans to specify, as part of the revisions to 40 CFR Part 142, the materials States are to submit to EPA so the Agency can determine whether a State has adopted requirements that are no less stringent than the Federal NPDWRs. State program revisions that occur before changes to 40 CFR Part 142 are promulgated must, however, be reviewed by EPA as well. States must demonstrate to EPA that their program revisions allow them to continue to meet the requirements of section 1413 (a) of the SDWA and 40 CFR 142.10 of the Implementation regulations. For example, EPA must review the State's implementing statutory and regulatory changes. It may be necessary in some instances for States to provide a State Attorney General's opinion specifically explaining how the State's statutes and regulations give it the authority to implement and enforce the new requirements. Specific to the program revisions contained in today's Federal notice, States must also provide their methodology for determining the vulnerability of a public water system as this is an integral part of determining the public water system monitoring requirements. States should provide this information to EPA through the applicable EPA Regional Office. To ensure consistency with Federal requirements, EPA encourages States to involve the Regional Offices during the developmental stages of any new statutes or regulations rather than waiting until after final adoption

It is important that public water systems be aware of their responsibilities under the Federal

regulations. Systems in States without primacy are subject to the Federal requirements on the effective date of the NPDWRs, i.e., 18 months from publication in the Federal Register (except for monitoring requirements which are effective January 1, 1988). Public water systems located in States which do not have primacy shall forward all analytical results and other information required by this regulation to EPA directly.

Systems located in States which have primacy, but have not adopted the requirements contained in this regulation, must comply with Federal requirements. Failure by a State with primacy to establish its own requirements does not exempt a system from the Federal requirements and systems which violate a Federal requirement contained in this regulation will be subject to Federal enforcement. Public water systems located in States with primacy should, however, report analytical results and all other information required by this regulation to the State even if the State has not yet adopted the requirements of the regulation. It will be the responsibility of the State, in such cases, to forward information to EPA.

4. Monitoring, Quality Control, and Records

Under section 1401(1)(D) of the Act, NPDWRs are to contain "criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels; including quality control and testing procedures to insure compliance with such levels . . ." In addition, Section 1445 states that, "every person who is a supplier of water . . . shall establish and maintain such records, make such reports, conduct such monitoring and provide such information as the Administrator may reasonably require by regulation to assist him in establishing regulations, . . . in evaluating the health risks of unregulated contaminants or in advising the public of such risks." Section 1445 also requires EPA to promulgate regulations requiring every public water system to conduct a monitoring program for unregulated contaminants.

5. Non-transient Non-community Water Systems

Public water systems are defined in the Act at section 1401(I)(D)(4) as those systems which provide piped water for human consumption and have at least 15 connections or regularly serve at least 25 people. The category "public water system" is composed of community and non-community water systems. The community water system is one which serves at least 15 connections used by year-round residents or regularly serves at least 25 year-round residents (40 CFR 141.2). Non-community systems, by definition, are all other water systems. Non-community systems include transient systems (e.g., campgrounds, gas stations) and non-transient systems (e.g., schools, workplaces, hospitals which have their own water supply and serve the same population over six months of a year), as explained in more detail later.

6. Public Notification

Section 1414(c) of the Act requires the owner or operator of a public water system which fails to comply with an applicable maximum contaminant level or treatment technique requirement, testing procedure, or section 1445(a) monitoring requirement to give notice to the persons served by the water system. Owners and operators of public water systems for which variances or exemptions are in effect, or which fail to comply with the requirement of any schedule imposed pursuant to a variance or exemption, must also give notice. Section 1445(a)(5) also requires public water systems to notify the persons served by the water system and the Administrator of EPA of the availability of the results of monitoring for unregulated contaminants.

B. Regulatory Background

CLW

On June 12, 1984 (49 FR 24330), EPA proposed MCLGs for the eight VOCs covered in today's notice: Benzene, carbon tetrachloride, 1,2-dichloroethane, trichloroeth (0,0,0) 1 5 5

dichloroethylene, 1,1,1-trichloroethane, para-dichlorobenzene, and vinyl chloride. On November 13, 1985, EPA published the final MCLGs and proposed MCLs for these eight VOCs (50 FR 4680) and 50 FR 46902). Detailed discussions of the history of the regulation of VOCs in drinking water together with information on occurrence in drinking water and any adverse effects of human exposure were presented in these notices. This background is summarized below. EPA proposed to amend the MCLG for para-dichlorobenzene (p-DCB) and reproposed the MCL for p-DCB on April 17, 1987 (52 FR 12876).

1. MCLGs, MCLs, and Monitoring

In the November 13, 1985, notice for substances considered to be known or probable human carcinogens, EPA set the MCLGs at zero. For substances it did not consider known or probable human carcinogens, EPA set the MCLGs based upon chronic toxicity data. Table 1 summarizes the final MCLGs for these VOCs. The Chemical Manufacturers Association, the Halogenated Solvents Industry Alliance, and the Natural Resources Defense Council each filed petitions for review of one or more of these MCLGs. These petitions are pending before the U.S. Court of Appeals for the District of Columbia Circuit.

The establishment of an MCLG at zero does not imply that actual harm would necessarily occur to humans at a level somewhat above zero, but rather that zero is an aspirational goal, which includes a margin of safety, within the context of the Safe Drinking Water Act. MCLs, even though set at levels above aspirational MCLGs, based on feasibility considerations, are also considered safe levels that are protective of public health.

EPA proposed the MCLs for the eight VOCs based upon an evaluation of (1) the availability and performance of treatment technologies [Best Technology Generally Available (BTGA), under Sections 1412 and 1415, was identified as PTA or GAC], (2) the availability, performance, and cost of analytical methods, and (3) an assessment of the costs of application of various technologies to remove VOCs from drinking water to various concentrations. Table 1 summarizes the final MCLGs and the proposed and final MCLs that EPA is promulgating in this rule.

TABLE 1. -- FINAL MCLGS AND PROPOSED AND FINAL MCLS FOR THE VOCS

Compound	Final MCLG (mg/1)	Proposed MCL (mg/	Final MCL (mg/l)	
Benzene	Zero	0.005	0.005	
Vinyl chloride	Zero	.001	.002	
Carbon tetrachloride	Zero	.005	.005	
1,2-Dichloroethane	Zero	.005	.005	
Trichloroethylene	Zero	.005	.005	
p-Dichlorobenzene *	0.075	.005	.075	CLW
1,1-Dichloroethylene	.007	.007	.007	A & A
1,1,1-Trichloroethane	.20	.20	.20	0000001596

^{*} Reproposed on April 17, 1987, at zero and 0.005.

As described above, the Agency proposed to amend the MCLG and reproposed the MCL at 52 FR 12876 (April 17, 1987) for para-dichlorobenzene (which is the common name for 1,4-dichlorobenzene). These proposals were based upon results of a new National Toxicology (NTP) study. Based on a preliminary assessment of the total weight of evidence of the toxicological studies, EPA proposed to reclassify p-dcb as a Group B2 substance under the Agency's Guidelines for Carcinogen Risk Assessment at 51 FR 33992 (September 24, 1986).

This notice on p-dcb also indicated that EPA was considering classification of p-dcb in Group C instead of B2. The Agency asked for public comment on the appropriate classification bassed on the weight of evidence.

In the November 1985 notice, EPA proposed to require non-transient non-community water systems to meet the same requirements as community water systems by broadening the definition of "community water systems." This category of public water systems includes such systems as schools and factories where the same consumers may be exposed not only for part of the day but throughout much of the year, and often for many years.

At the same time that EPA proposed the MCLs, it also proposed minimum compliance monitoring requirements consisting of one initial round of monitoring to determine the extent of contamination and certain follow-up monitoring requirements if the initial round of monitoring indicated VOC contamination. The November 1985 notice also proposed monitoring requirements for 51 additional unregulated contaminants (all VOCs) under Section 1445. These requirements were very similar to the compliance monitoring requirements proposed for the eight MCLs. The major difference was that for the unregulated contaminants only one round of monitoring was proposed (the compliance monitoring requirements called for repeat sampling ranging in frequency from quarterly to every 5 years, depending on the prior monitoring results and a determination of a system's vulnerability to contamination.

2. Reporting and Public Notice

EPA also proposed reporting and public notice requirements for VOCs in the November 19985 notice. The proposed requirements were identical to those currently in place under the National Interim Primary Drinking Water Regulations (now simply "National Primary Drinking Water Regulations"). No change in the public notice requirements was proposed at that time.

For unregulated contaminants, the proposed regulations would have required the PWS $t\infty$ notify its consumers of the availability of the analytical results of the unregulated contaminant monitoring and to submit a representative copy of each public notice to the State. In addition, the results of the monitoring were to be submitted to the State.

In response to the SDWA amendments of 1986, which revised the public notification requirements in Section 1414(c), EPA recently proposed changes to public notification requirements in 52 FR 10972 (April 6, 1987). That proposal includes specific explanation is of the potential health risks of exposure to the eight VOCs in today's final rule. Those explanations were proposed to be required in each public notice for failure to comply with any MCL.

C. Public Comments on the Proposal

EPA requested comments on all aspects of the November 13, 1985, proposal and the Aprril 17, 1987, reproposal. A detailed summary of the comments received and the Agency's responses are presented in the document "Summary of Comments and EPA responses on the Proposed MCLs for the VOCs, Reproposed MCLG/MCL for para-Dichlorobenzene, and Requirements for Monitoring Unregulated Contaminants," available in the public docket. General summariæs of comments, with responses, pertaining to specific MCL issues are presented in the relevant sections of this notice.

EPA received over 250 written comments on the November 1985 proposed rec. Meluding 39 from individuals, 20 from companies, 45 from water utilities or water utility associations, 10 from trade associations, 101 from Federal agencies, States, and local governments, and 44 from other groups (primarily mobile home park operators). EPA (100 d) public healing in Washington, D.C., on January 13, 1986, and received an additional 10 comments at that time. Additional comments were received at the May 4, 1987, public hearing as well as im writing during the public comment period on the April 1987 reproposed MCLG and MCL from

para-dichlorobenzene.

III. Explanation of Today's Actions

A. Non-Transient Non-Community Water Systems

In the November 1985 notice, EPA proposed to redefine the term "community water system" to include certain non-community water systems as follows:

Community Water System means a public water system which serves at least 15 service connections used by year-round residents or regularly serves at least 25 of the same persons over 6 months per year.

The purpose of the change was to protect nonresidential populations of more than 25 people who, because of regular long-term exposure, might incur long-term risks of adverse health effects similar to those incurred by residential populations. The change was designed to include systems serving more than 25 persons in such places as workplaces, offices, and schools, that have their own water supplies.

EPA requested comment on this proposal. About half the commenters who addressed this issue supported the change, citing the potential health risks from exposure in these non-transient situations. The other commenters stated that the resource burden to the States and the regulated community would be excessive and felt that the potential benefits would not outweigh the costs.

EPA believes applying NPDWRs to such systems is protective of public health and should be implemented. EPA believes the risks to consumers commonly associated with long-term exposures to contaminated drinking water in many cases could also apply to NTNCWS drinking water consumers, such as factory employees and school children exposed to the same drinking water source over a number of years. The chronic health risks to consumers in non-transient water systems would be similar to residential populations served by community water systems, since one can estimate that one-third to one-half or more of the normal daily water consumption would occur at the school or workplace, and the rest at home. Therefore, EPA believes it is appropriate to apply NPDWRs to both community and non-transient non-community water systems. However, water from systems serving populations for only a brief time (e.g., campgrounds, parks, gas stations) does not pose long-term health risk such as those associated with the VOCs. Therefore, EPA believes that it is not necessary to regulate water systems that only serve transient population for agents of chronic exposure but these water systems should be regulated for acute risks (e.g., nitrates).

Instead of amending the definition of community water systems, as proposed in the November 1985 notice, EPA is promulgating a definition of "non-transient, non-community water systems" and applying the NPDWRs for the eight VOCs to those systems (as well as community water systems, as currently defined in EPA's regulations). This term includes the universe of non-transient systems that EPA included in the revised definition of community water systems it proposed. This approach is preferable to the proposed approach because if EPA amended the definition of "community water system" to include non-transient non-community systems, then all of the existing NPDWRs would apply to those systems by definition. This is not EPA's intent. However, EPA does intend to apply future NPDWRs to non-transient non-community water systems as it evaluates and revises the existing regulations, as required by the 1986 amendments to the SDWA. In conclusion, EPA is amending 40 CFR 141.2 to add a new definition as follows:

A "non-transient non-community water system" means a public water system that is not a community water system and that regularly serves at least 25 of the same persons over six months per year.

B. MCLG for Para-dichlorobenzene

In this notice, EPA has placed p-dcb in the Group C category (limited evidence of carcinogenicity in animals). (See <u>51 FR 33992</u>, September 24, 1986, for a full discussion on EPA's Guidelines for Carcinogenic Risk Assessment.) On November 13, 1985, the Agency promulgated an RMCL for p-dcb as a Group D substance, based on chronic toxicity data from the studies available at that time.

After that notice was published, the Agency received the results of a long-term study on p-dcb conducted by the National Toxicology Program (NTP) (Ref. 6). The NTP study was a chronic bioassay which used F344 rats and B6C3F1 mice. Tumors were found in both species of animals at incidences which were statistically significant. Therefore on April 17, 1987 EPA reproposed the MCLG for p-dcb. The EPA proposed the MCLG considering a classification of B2 for p-dcb but acknowledged the controversy surrounding this classification and presented an alternative Group C classification. Public comments were solicited on whether p-dcb should be classified as a B2 or C substance. The conclusions of these comments received on this proposal differed even though they were using the same criteria in the guidelines; eight commenters would place p-dcb in group C, two in Group B2.

The Agency recognizes that as with most chemicals, the evaluation of the carcinogenicity potential of p-dcb in humans is a difficult and somewhat controversial activity, in light of divergent interpretations made by the scientific community. Because it is necessary for the Agency to make a judgment based on a reasonable weighing of the evidence from the data at hand, at this time p-dcb is being classified in category C (possible human carcinogen).

At issue in the controversy of the classification is whether there exists "sufficient" evidence of carcinogenicity (i.e., B2 classification) or whether there is only "limited" evidence of carcinogenicity (i.e. Group C).

A Group B2 substance is defined by the following factors:

An increased incidence of malignant tumors or combined benign and malignant tumors in:

- (a) Multiple species or strains,
- (b) In multiple experiments (e.g., with different dose levels and routes of exposure) or
- (c) To an unusual degree in a single experiment with regards to a high incidence, unusual site or type of tumor, or early age at onset.

A Group C is defined by the following factors:

Having limited animal evidence of carcinogenicity in the absence of human data in which:

- (a) The studies involve a single animal species, strain or experiment and do not meet criteria for sufficient evidence.
- (b) The experiments are restricted by inadequate dosage levels, inadequate duration of exposure, or inadequate reporting, or
- (c) The studies show an increase in the incidence of benign tumors only.

As pointed out in these Guidelines, this classification is not meant to be applied rigidly or mechanically, but a balanced judgment of the totality of the available widence needs to be considered. This weight of the evidence approach can increase the number of reasonable interpretations to the same data base.

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Decision Process

Evaluating the increased male rat kidney tumors and liver tumors in male and female rmice of the NTP 1986 bioassay, p-dcb might be tentatively classified in Group B2; probable hurman carcinogen. However, when reviewing the total weight of evidence at this juncture, p-d lcb could also be classified in Group C; possible human carcinogen. Factors relevant to determining weight of evidence include: 1) evidence of carcinogenicity, 2) structure/activity relationships, 3) genotoxicity test findings, and 4) results of appropriate pharmacokine tic and toxicological observations.

Because the carcinogenicity bioassays (discussed under *Evidence of Carcinogenicity*) do not provide unequivocal evidence of carcinogenic potential for humans, it is necessary to consider all factors in determining the weight of evidence for p-dcb carcinogenicity.

(1) Evidence for Carcinogenicity. Evidence for the carcinogenicity of p-dcb is primarily | imited to the NTP study of F344 rats and B6C3F1 mice. In this study, rats and mice were expcosed to two doses of p-dcb in corn oil administered via gavage. The NTP concluded that there was clear evidence of carcinogenicity both for male rats as shown by an increased incidencee of renal tubular cell adenocarcinomas and for mice of both sexes as shown by increased incidences of hepatocellular carcinomas and hepatocellular adenomas. No evidence of carcinogenicity was seen in female rats.

The issue in interpreting the guidelines is to determine the relevance of both the male **m**at kidney and mouse liver tumors to human carcinogenesis.

Induction of male rat kidney tumors by several nongenotoxoc organic chemicals has been linked to the presence of hyaline droplets composed of alpha-2u-globulin, a protein which has not been detected in female rats, mice or humans. There is evidence for the formation of hyaline droplets in male rats given p-dcb orally. It has been asserted by several investingators and commenters, and supported by substantial data, that alpha-2u-globulin is essentiall for hyaline droplets in the male rat kidney. Presence of hyaline droplets seen only in the male rat kidney, which was the target organ in the NTP bioassay, and lack of hyaline droplets in the female rat kidney, which was not a target organ, supports the hypothesis that hyaline droplets formation may have limited significance for human exposure to p-dcb. The mechanism of carcinogenesis is not absolutely certain but the involvement of alpha-2u-globulin is a probable and sound scientific explanation that has been developed from a large body of mechanistic and pharmacokinetic studies on this chemical.

The significant increase in mortality indicated that the MTD was exceeded for the high close male rats.

Diminished toxicological significance might be ascribed to mouse liver tumors, which are induced by a number of chlorinated hydrocarbons. As with tumors of the male rat kidney, theories have been proposed which argue that the mouse liver response is not relevant: to humans. Explanations are still tentative and the possible relevance to human carcinogenicity is a current topic of debate.

Other bioassays have been performed which although having some shortcomings confirm the negative results in the low dose NTP bioassay results. Alderly Part Wistar rats were exprosed to multiple doses of p-dcb via inhalation for 76 weeks, followed by an additional 36 weeks of observation (Riley et al., 1980; described in Ref. 8). No increases in tumor incidence of the were observed. Comparisons of this study with the NTP bioassay are made difficult because of the differences in the route and duration of exposure. However, if 0.1 liter/minute was assumed as the breathing rate for 500 gram rats exposed to p-dcb for five hours (lag, frive 6 0 days/week for seventy-six weeks, the estimated daily oral dose would be 178 mg/kg. This estimated dose is slightly higher than the low dose of 150 mg/kg in male rats, which di id not produce a significant increase in kidney tumors, as reported from the NTP study. While the

shorter duration of exposure may be responsible for diminished tumorigenic response, the variety of toxic effects (increase in liver, kidney, heart and lung weights, increase in urinary protein and coproporphyrin output) in the high dose group (500 ppm) indicate that the MTD was approached.

Subchronic studies have demonstrated evidence of liver and kidney toxicity and a variety of other toxic effects from p-dcb exposure to animals either via gavage or inhalation (Hollingsworth, 1956, 1958; described in Ref. 8). No evidence of carcinogenicity was found, but the short duration of these studies (6-month duration) precludes detecting carcinogenic effects unless the latency would be unusually short and the compound were a potent carcinogen.

No evidence of carcinogenicity in humans has been reported, which is not unusual. Therefore, inadequate data are available to assess the weight of evidence for carcinogenicity from epidemiological/case studies in humans.

Thus, considering the totality of evidence, the available bioassay data are equivocal as a basis for extrapolating to humans and the epidemiological data are inadequate. In the judgment of the Agency, a Group C classification for p-dcb would be more appropriate than a B2 classification based upon the information currently available.

(2) Structure-Activity. Compounds with similar chemical structures have been tested in longterm carcinogenicity bioassays, but no clear evidence of carcinogenicity has been reported. Such structure-activity information can be useful when evaluating closely related chemicals.

Two compounds with similar structures to p-dcb (orthodichlorobenzene (o-dcb) and monochlorobenzene (mcb)) have been tested in NTP bioassays. As with p-dcb, the compounds were administered in corn oil via gavage to F344 rats and B6C3F[1] mice. Under test conditions, o-dcb was not carcinogenic at doses of 60 and 120 mg/kg administered for 103 weeks. For mcb, an increase of neoplastic nodules of questionable statistical significance was found for high-dose male rats (120 mg/kg). Both o-dcb and mcb have been classified as Group D: inadequate evidence for carcinogenicity.

Metabolites of p-DCB (2,5-dichlorophenol and its hydroquinone) have not been tested for carcinogenicity, 2,4-Dichlorophenol was administered in drinking water in a two-year bioassay in rats (Exon and Koller, 1985; described in Ref. 8) and found to produce no increase in tumors, but was cocarcinogenic when administered with ethylnitroso urea (ENU). 2,4-Dichlorophenol has not been formally classified, but could be categorized as Group D: inadequate evidence for carcinogenicity.

Structure activity relationships alone cannot be the sole basis for discounting positive findings, but they do detract from the overall weight of evidence of carcinogenicity in this case.

(3) Genotoxicity Tests. p-Dcb was determined not to be genotoxic from a variety of shortterm genotoxicity bioassays. Therefore, it is less likely that it could be carcinogenic by a genotoxic mechanism. Genotoxicity is often associated mechanistically with carcinogenicity. Some non-genotoxic substances are carcinogenic by unknown mechanisms.

p-Dcb is not mutagenic when tested in Salmonella typhimurium or in the E. coli WP2 system. Increased frequency of back mutation was observed on the methionine requiring forms in the fungus Aspergillus nidulans, however this finding is not considered significant.

p-Dcb was not found to induce forward mutations in mouse lymphoma cells, sister chromatid exchange in Chinese hamster ovary cells or unscheduled DNA synthesis in human lymphocytes. Negative results were also obtained in cytogenicity studies with rat bone marrow cells and a dominant lethal study in CD-1 mice following exposure to p-dcb.

(4) Pharmacokinetic and Toxicological Observations. Commenters also raised questions on the relevance of the results of the NTP bioassay to exposure of humans to p-DCB via drink water. Issues include the toxicological significance of the mode of administration (gavage vs. drinking water) and the vehicle used (corn oil vs. drinking water).

With respect to both mode of administration and vehicle, no data are available specifically on p-dcb, but bioassays on other chlorinated hydrocarbons have shown that the pharmacokinetics of absorption/distribution differ between compounds administered in corn oil via gavage compared to drinking water administration. The issue that the corn oil vehicle itself may affect hepatic metabolic capabilities and influence the susceptibility of the mouse to hepatic tumors has been a subject of controversy. No. data are available specifically on p-dcb.

Conclusion

Therefore, in considering the total weight of evidence: One positive study in two animal species, a partially corroberating study in one species, no human evidence, no replication of the results in animals, negative evidence of carcinogenicity in structurally similar compounds, negative mutagenicity studies, uncertainties with mode of administration and controversy surrounding the significance of the rat kidney and mouse liver tumor results, at this time the EPA establishing the MCLG and MCL for p-DCB considering p-dcb as a Group C carcinogen.

The classification of p-dcb as a Group B2 or Group C substance is a controversial one. EPA will reassess this classification as new information becomes available. This reclassification results in a reduction of the prior MCLG (RMCL) by a factor of 10 from 0.75 to 0.075 mg/l.

An MCLG of 0.075 mg/l (75 mu g/l) has been calculated based on chronic toxicity data. The MCLG was calculated as follows:

DWEL = reference dose X body weight / daily water consumption = (0.1 mg/kg/day)(70g) / 21/day = 3.75 mg/l

MCLG = drinking water equivalent level X relative source contribution / additional uncertainty factor

 $MCLG = 3.75 \times 0.2 / 10 = 0.075 \text{ mg/l} (75 \text{ mu g/l})$

Where the reference dose is calculated as:

RfD = no observable effect level / uncertainty factor = 150 mg/kg/day (5) / 1000 (7) = 0.1 mg/kg/day

The classification of Group C is also consistent with the recommendations of the National Drinking Water Advisory Council, the transcript of a meeting held by the Halogenated Solvents Subcommittee of the EPA Science Advisory Board on p-dcb. Eight out of the ten commenters who responded to the request for comment of the para-dichlorabenze classification supported the Class C decision.

Had p-dcb been assigned to Group B2, the 95% upper-limit carcinogenic potency factor for humans, q[1]*, would be the basis for the quantitation. A "what if" calculation for p-dcb, using the draft q[1]* value is 2X10<-2>(mg/kg/day)<-1> by the multistage model and male mouse liver tumor data indicated an upper-limit individual lifetime cancer risk of 4X10<-5> for a 70 kg human drinking 2 L/water a day for a lifetime (assumed to be 70 years) exposure to drinking water containing 75 mu g/L.

C. MCLs for VOCs

In this rule, EPA is promulgating MCLs for the eight VOCs as follows:

	Final MCL
Compound	(mg/1)
Benzene	0.005
Vinyl chloride	0.002
Carbon tetrachloride	0.005
1,2-Dichloroethane	0.005
Trichloroethylene	0.005
para-Dichlorobenzene	0.075
1,1-Dichloroethylene	0.007
1,1,1-Trichloroethane	0.2

As noted earlier, section 1412(b)(4) of the Act requires EPA to set MCLs as close to the MCLGs as is feasible. Section 1412(b)(5) of the Act defines "feasible" to mean "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration)," i.e., "BAT."

This provision represents a change from the provision prior to 1986, which required EPA to judge feasibility on the basis of "best technologies generally available" ("BTGA"). The 1986 amendments changed BTGA to BAT and added section 1412(b)(5), which specifies that the technology selected as BAT must be tested for efficacy under field conditions, not just under laboratory conditions. The legislative history explains that Congress removed the term "generally" to assure that MCLs "reflect the full extent of current technology capability." [S. Rep. No. 56, 99th Cong., 1st Sess., at 6 (1985)]. Read together with the legislative history, EPA has concluded that the statutory term "best available technology" is a broader standard than "best technology generally available" and that this standard allows EPA to select a technology that is not necessarily in widespread use, as long as it has been field tested beyond the laboratory. In addition, EPA believes this change in the statutory requirement means that the technology selected need not necessarily have been field tested for each specific contaminant. Rather, EPA may project operating conditions for a specific contaminant using a field tested technology from laboratory or pilot systems data.

Based on the statutory directive for setting MCLs, EPA derives the MCLs from an assessment of a range of pertinent factors, including the availability and performance of BAT, the costs of these technologies for different size water systems, and the number of water systems that would have to install technologies. EPA also evaluates the availability of analytical methods and the reliability of analytical results as well as the resulting health risks of various contaminant concentration reduction levels attainable by BAT. For drinking water contaminants, the target reference risk range for carcinogens is 10<-4> to 10<-6> and most regulatory actions in a variety of EPA programs have generally fallen in this range using conservative models which are not likely to underestimate the risk. Of course, MCLs could be set outside the range depending upon the feasibility of achieving a specific level.

1. Treatment Technologies

As explained in the November 1985 proposal, EPA examined a number of treatment processes for their potential to reduce the level of VOCs in drinking water. These technologies are discussed in the document "Technologies and Costs For The Removal of Volatile Organic Chemicals From Potable Water Supplies." (Reg. 2). (A draft of this document was available at the time of the proposal. The final document is available from the National Technologies and Costs For The Removal of Volatile Organic Chemicals From Potable Water Supplies." (Reg. 2). (A draft of this document was available at the time of the proposal. The final document is available from the National Technologies and Costs For The Removal of Volatile Organic Chemicals From Potable Water Supplies." (Reg. 2) (A draft of this document was available at the time of the proposal. The final document is available from the National Technologies.)

In reviewing the different technologies available, EPA looked at the following factors: Removal efficiency, degree of compatibility with the other water treatment processes, service life, and the ability to achieve compliance for all the water in a public water system.

Based on these criteria, in the November 1985 notice, EPA proposed granular activa ted carbon (GAC) and packed tower aeration (PTA) as "best" technologies for removing VOCs from drinking water. As described in that notice (50 FR 46914), these technologies have the following characteristics: good removal efficiencies (90 to 99 percent); compatibility with other types of water treatment processes; reasonable service life; and ability to ach leve compliance for all the water in a public water system. In addition, these two technologies are commercially available and have been used successfully to remove VOCs in ground water from both influents and effluents in many locations across the United States.

In the 1986 amendments to the Safe Drinking Water Act, Congress specified in section 14:12 (b)(5) of the Act that:

granular activated carbon is feasible for the control of synthetic organic chemicals, and any technology, treatment technique, or other means found to be the best available for the control of synthetic organic chemicals must be at least as effective in controlling synthetic organic chemicals as granular activated carbon.

For all the VOCs except vinyl chloride, EPA has identified GAC as technology that is effectiwe for removing VOCs. PTA is equally effective. Therefore, these two technologies are "best" for these seven VOCs. PTA is more effective than GAC for vinyl chloride, as noted below.

Vinyl chloride differs from the other VOCs because it is a gas under typical temperature an id pressure conditions. Therefore, vinyl chloride is most easily removed by PTA treatment. Because vinyl chloride is a gas and a known human carcinogen, no laboratory isotherms heave been developed by EPA or reported in the literature. However, one investigator reported sporadic removal of vinyl chloride from ground water in Florida using GAC (Symons, 1978)0. This investigator also noted that vinyl chloride was the only one of a number of related, low molecular weight VOCs to show such an erratic pattern. A more recent, unpublished study of ground water in Wisconsin (EPA, 1987) showed less erratic removals at a higher empty bead contact time and lower raw water concentrations. It is difficult to interpret either of these studies. Therefore, because PTA has been demonstrated to be extremely effective and GAC may, under some circumstances, exhibit poor or erratic removal, EPA is not specifying GAC as "best" for the removal of vinyl chloride. PTA, however, is "best" for removal of this contaminant.

Also, it should be noted that the data used to determine removal efficiencies were b ased on performance for ground water. EPA expects that GAC, applied to surface water, would achi ieve lower performance efficiencies because of the higher levels of organic carbon found in surface water which cause more rapid depletion of the capacity of the GAC (ground waters typically have very low levels of background organic carbon) (See Reference 2).

In addition to GAC or PTA, there are other technologies which may remove VOCs from drinking water, e.g., resins, powdered activated carbon. However, EPA, has concluded that these technologies are inferior to GAC and PTA for various reasons, e.g., the technology is not commercially available or the removals are lower and/or less consistent. For a further discussion of other technologies EPA considered, and why they are not designated as "best;" see EPA's technology and cost document (Reference 2).

2. Costs

As noted above, EPA is to set the MCL as close to the MCLG as "feasible," which is defined as "feasible with the use of the best technology . . . which the Administrator finds . . . is available (taking costs into consideration)." Section 1412(b)(5). In considering costs to

determine whether the "best" technology is "available," (i.e., BAT), the legislative history of both the Safe Drinking Water Act of 1974 and the 1986 amendments indicates that EPA is to consider whether the technology is reasonably affordable by regional and large metropolitan public water systems [see H.R. Rep. No. 93-1185, p. 18 (1974) and statement of Senator Durenberger, Vol. No. 132 Cong. Rec. S6287 (daily ed., May 21, 1986)].

To determine BAT, EPA evaluated the costs associated with the technologies it considered "best," i.e., GAC and PTA. EPA estimates the total costs of removing each of the eight VOCs (in 1983 dollars) for both GAC and PTA based on 90-99 percent removal (i.e., form 0.5 mg/1 to 0.005 mg/1). EPA looked at these costs for large systems (i.e., systems serving 100,000 to 500,000 people), medium systems (i.e., systems serving 3,300 to 10,000 people), and small systems (i.e., systems serving 100 to 500 people).

Costs for large to medium systems range from 10 to 85 cents/1,000 gallons for GAC and five to 30 cents/1,000 gallons for PTA. Costs are higher for small systems; for instance, benzene removal using GAC would cost approximately \$1.50/1,000 gallons, and removal using PTA would cost 86 cents/gallon. For concentrations of VOCs expected in ground waters, GAC can achieve a level of 0.005 /mg/l at reasonable empty bed contact times and carbon usage rates. This is reflected in the costs displayed in Table 5. The costs are based on carbon usage rates that estimate breakthrough at three to six months; however, in a number of locations GAC has achieved VOC levels below detection for 12 months or longer. The empty bed contact time is reflected in the capital costs and carbon usage rates in the annual O&M costs. EPA believes that the costs incurred by even the smallest system size (25-100 people) are reasonable and affordable. (Reference 2).

While most commenters agreed with the cost estimates presented in the proposal, several claimed that the Agency's treatment cost estimates were too low. EPA believes that the range of treatment cost estimates are representative. The differences between EPA's estimates and those presented by the commenters are due to the unique site-specific factors considered by the commenters (e.g., variations in costs of land, zoning requirements for tower height, housing for columns, and labor and material costs).

Some commenters stated that the Agency should consider the cost of air pollution control for VOC emissions from packed tower aeration. EPA does not believe that it is appropriate to factor the cost of air pollution control into the treatment costs since assessments show air emissions to be negligible from aeration treatment of drinking water to remove VOCs (See Ref. 5, Peters and Clark, 1985). For further information on air emissions of VOCs, see the November 1985 notice (50 FR 46911, November 13, 1985).

For contaminants with MCLGs set at a non-zero level (substances in carcinogenicity Group C, D, or E), i.e., 1,1-dichloroethylene, 1,1,1-trichloroethane, and para-dichloroben zene, EPA has concluded that the removal costs cited above are affordable. Therefore, because these technologies meet the treatment criteria and the costs are reasonable, GAC or PTA are BAT for these three contaminants. Since these technologies can easily remove these contaminants to levels below their MCLGs, it is feasible to set MCLs equal to the MCLGs. EPA has set the MCLs accordingly.

For contaminants with MCLGs at zero (substances in either Group A or B), the analysis is somewhat different because detection and achievement of zero concentration in principle cannot be achieved. In the MCL-setting process, therefore, EPA evaluates the feasibility of achieving levels as close to zero as feasible. Based on the costs and the availability/performance of treatment described above, EPA has concluded that GAC and PTA are BAT (except that GAC is not BAT for vinyl chloride, since it is not the "best" technology).

To determine what level was feasible as BAT, EPA examined the total compliance costs at various levels of contamination (as well as the individual compliance costs adminarized above). For all the contaminants with MCLGs at zero, except for vinyl chloride, if the MCLs

were set at 0.005 mg/l, EPA estimates that 1300 CWS would need to install treatment at a total capital cost of \$280 million to achieve compliance. If EPA set the MCLs at 0.001 mg/l for these contaminants, EPA estimates that many more systems, i.e., a total of 3800, would have to install treatment at a total capital cost of \$1,300 million to achieve compliance. EPA believes that, considering the efficacy and the nationwide costs associated with these different levels, as specified in the Act, the costs associated with the additional removals, i.e., from 0.005 mg/l to 0.001 mg/l, are not warranted. Therefore, the Agency has established MCLs for trichloroethylene, carbon tetrachloride, 1,2-dichloroethane, and benzene at 0.005 mg/l.

For vinyl chloride, EPA has set the MCL at 0.002 mg/l. This lower level reflects the treatment capability of PTA that would be used to remove vinyl chloride, and it is not expected to result in any increased cost over an MCL of 0.005 mg/l. EPA believes that very few, if any, public water systems will need to install treatment solely to control vinyl chloride. Because systems with vinyl chloride present at any level virtually always have one or more of the other VOCs covered by this rule present at levels higher than the promulgated MCL for these VOCs, these systems will be treating their water to comply with the MCLs applicable to those other VOCs and the same treatment (PTA) will also remove the vinyl chloride to 0.002 mg/l.

EPA estimates the total compliance costs to meet the eight MCLs at \$300 million (total present value costs) and \$22.5 million (total annual costs) (See Ref. 3, "Economic Impact Analysis of Proposed Regulations"). EPA estimates the annual cost per family to be \$41 per year for a small system, \$12 per year for a medium system, and \$3 per year for a large system.

3. Other Factors

The other factors EPA examined support its MCL determinations. They are explained below.

Analytical Methods. The Agency also examined the analytical methods available for the measurement of volatile organic chemicals in drinking water and summarized its findings in the November 1985 notice. Based on this review, the Agency has determined that analytical methods currently exist which can reliably measure VOCs in drinking water. In addition, EPA has concluded that the cost of sample analysis at intervals necessary to assure detection of MCL violation is economically feasible for all public water systems. Costs are estimated to be approximately \$150 to \$200 per sample analysis. Further discussion of available analytical methods is included in the section on compliance monitoring. The MDL is the minimum concentration of a substance that can be measured and reported with 99 percent confidence that the true value is greater than zero. These MDLs are the result of measurements made by a few of the most experienced laboratories under non-routine and controlled ideal research-type conditions.

MDLs and PQLs. The MDL is used by individual laboratories to determine the laboratory-specific minimum detection capabilities. EPA has gathered information indicating that laboratories in general are able to achieve MDLs of 0.0005 mg/l or lower with the available VOC methods (Ref. 1). Specifically, under single-laboratory, ideal conditions, the method detection limits (MDLs) of the eight VOCs have been determined to range from 0.0002 to 0.0005 mg/l.

In the November 1985 proposal, EPA defined the "practical quantitation level" (PQL) as the lowest level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions. PQLs thus represent a level considered to be achievable on a routine basis. The basis for setting PQLs is (1) quantitation, (2) precision and accuracy, (3) normal operations of a laboratory, and (4) the fundamental need (in the compliance monitoring program) to have a sufficient number of laboratory aliable to conduct the analyses.

The PQL is analogous to the limit of quantitation (LOQ) as defined by the American Chemica II Society. Both the LOQ and the PQL define the concentration of an analyte above which is the region of quantitation and below which is the region of less certain quantitation. The difference is that where the PQL is an inter-laboratory concept while the LOQ is specific to arn individual laboratory. The Agency developed the PQL concept to define a measurement concentration that is time and laboratory independent for regulatory purposes. The LOQ and MDLs, although useful to individual laboratories, do not provide a uniform measurement concentration that could be used to set standards.

PQLs for the VOCs were determined based on the MDL and surrogate test data. In the past, EPA has estimated the PQL at five to ten times the MDL and, in the November 1985 notice, EPA suggested setting PQLs at this general range. In the notice EPA used the results of interlaboratory studies to confirm this estimate. The PQLs based on these laboratory data are considered a "two-step removed" surrogate for actual laboratory performance, first because they are estimated from another measurement (the MDL) and second, because they are derived from laboratory performance under ideal circumstances. Therefore, they do not actually represent the results of normal laboratory procedures, but are a model of what normal procedures might achieve. Specifically:

- (1) Laboratories receive performance evaluation samples in which a limited number of concentrations are analyzed and the samples do not have matrix interferences as might actual samples;
- (2) PQLs are based on EPA and State laboratory data which are considered to be representative of the best laboratories, but not all laboratories; and
- (3) Samples are analyzed under controlled ideal testing conditions which may not be representative of routine practice.

For these reasons, the PQL represents a relatively stringent target for routine performance. EPA expects that the PQLs in this rule will push laboratories to perform at a higher level tharm they would otherwise. In the range between the MDL and the PQL, quantitation of contaminants can still be achieved, but not necessarily with the same precision and accuracy possible at the PQL. As measurements approach the MDL, there is much less confidence in quantitation. Thus, PQLs set a target performance level for laboratories using a specified set: of precision and accuracy limitations. In this manner, PQLs provide consistency in implementing a regulatory program, in a practical way, where both quality control and quality assurance is critical.

Most commenters agreed with the PQL concept; however, several stated that the PQLs shou Id be verified further through additional multi-laboratory studies. For instance, several commenters were critical of the PQL for vinyl chloride, stating that the level should be based on multi-laboratory data as opposed to simply being set at a value of five times the MDL. EPA agrees that the PQLs should be further verified; as explained in Reference 1, the Agency collected additional multi-laboratory data including data on vinyl chloride, and used these data to set the final PQLs.

One commenter felt that PQLs should be replaced with the LOQ concept as described above. . EPA does not agree that the PQL should be set based upon the LOQ because the LOQ is dependent on the precision attainable by a specific laboratory, which can vary from day to day as well as among laboratories. Thus, the LOQ is not designed to assess the performance of a large number of good laboratories; instead, it is laboratory-specific and therefore is not suitable for setting criteria for national standards.

Some commenters stated that the PQLs were set at too high a level and suggested 0.001 mg/l, while others believed that the PQLs were too low. A PQL range from 0.071004 mg/l 7 for benzene was suggested by one commenter.

EPA disagrees with the comments that the PQLs were set at the wrong level; the levels were selected based on multi-laboratory data which confirmed the general rule of five to ten times the MDL. Setting the PQLs at higher or lower levels would not be consistent with the data. EPA recognizes that many laboratories have reported data at levels less than the PQL; however, the Agency does not consider the data sufficient upon which to base national standards considering the other data available. Again, PQLs provide for consistency in data quality from a diverse group of laboratories across the country, and provide routine performance goals that many laboratories must strive to achieve.

As explained in Reference 1, the PQLs are 0.005 mg/l for all the VOCs except vinyl chloride. EPA generally based the PQLs upon a laboratory performance criterion of +/-20 percent or 40 percent, depending on the concentration, for each individual VOC except for vinyl chloride which was +/-40 percent. This provides a relatively stringent performance target for laboratories but one that has been demonstrated to be achievable by three-quarters of the "best" (EPA and State) laboratories under evaluation conditions. It is expected that the remaining laboratories will need to upgrade their performance in order to meet this criterion. For vinyl chloride, the PQL is 0.002 mg/l (rounded from 0.0015 mg/l for the reasons discussed in Reference 1). The PQL of 0.002 mg/l recognizes that on the one hand the precision/accuracy associated with measuring vinyl chloride is expected to be less than for the other VOCs; but that, on the other hand, vinyl chloride is a known human carcinogen of high potency and the risk posed by each unit of exposure could be higher than for the other VOCs. Because of this latter factor, EPA believes it is appropriate to accept slightly less precise data in order to seek to obtain more stringent levels of control. Technical assistance to laboratories that wish to be certified to analyze vinyl chloride is available for EPA-EMSL in Cincinnati.

For each VOC, the PQL is equal to or less than the MCL. Therefore, laboratories will be able to reliably determine whether systems are in compliance with the MCLs.

Health Risks. EPA examined the theoretical maximum health risks expected at various contaminant levels. These health risks include non-cancer risks, as well as cancer risks. The upper-limit unit risk estimates from the animal data are derived from a linearized multistaged nonthreshold extrapolation model that is currently programmed as GLOBAL 83. Justification for its use is presented in EPA's Guidelines for Carcinogenic RISK Assessment. While recognizing that alternative statistical modeling approaches exist (e.g., one-hit, Weibull, log-probit and logit models, and maximum likelihood estimates), the range of risks described by using any of these modeling approaches has little biological significance unless data can be used to support the selection of one model over another. In the interest of consistency of approach and of providing an upper bound estimate for the potential cancer risk, the Agency recommends the use of the linearized multistage model. EPA considers this model and resulting risk estimates to be an upper-limit value in the sense that the true risk is unlikely to be higher and may be lower. An established procedure does not yet exist for making "most likely" or "test" estimates of risk within the range of uncertainty derived by the upper and lower limit values.

Table 2 presents sample risk estimates calculated at the 95 percent confidence limit using the multi-stage model for the five VOCs which are considered known or probable human carcinogens. EPA's Carcinogen Assessment Group (CAG) calculated these numbers based on the assumption of two liters of water ingested daily over a lifetime of 70 years for a person weighing 70 kilograms (kg). The Agency calculates these risk estimates so that they are not likely to underestimate the actual risks, and are conservatively used to evaluate "worse case" scenarios for the purpose of regulatory impact analysis.

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TABLE 2 -- AN EXAMPLE OF UPPER BOUND LIFE-TIME CANCER RISK (10<-5>) ESTIMATES FOR VOCS CATEGORIZED AS KNOWN OR PROBA-BLE HUMAN CARCINGENS

	Concentration in		
	drinking		
	water	(mg/l)	
Compound	Estimate	Rounded	*
Trichloroethylene	0.026	0.03	
Carbon tetrachloride	.0027	.003	
1,2-Dichloroethane	.0038	.004	
Vinyl chloride **	.00015	.0002	
Benzene	.012	.01	

- * Risk levels are best represented by one significant figure because of the imprecise nature of the risk model extrapolations.
- ** Calculation using preneoplastic nodules. If preneoplastic nodules were not factored into the risk assessment, the estimated risk at 10<-5> is 0.02 mg/l.

As mentioned above, for contaminants in drinking water, the target reference risk range for carcinogens is 10<-4> to 10<-6> and the MCLs EPA is promulgating in this notice generally fall in this range. EPA considers these to be safe levels and protective of public health. This is supported by the concept expressed by the WHO 1984 Guidelines for Drinking Water Quality, where it selected a 10<-5> guideline value, and then explained that the application could vary by a factor of ten (i.e., 10<-4> to 10<-6>.

4. Summary of MCL Determinations

EPA considers the MCLs determined by this process to be safe and protective of the public health. Even though the MCLGs and MCLs for certain substances such as 1,1,1-trichloroethane and para-dichlorobenzene are relatively higher than those for the other VOCs, EPA does not mean to imply that systems should allow a drinking water supply to be contaminated up to those levels. Public water supplies should always strive to distribute drinking water of the highest quality feasible. In some cases, other factors such as taste and odor can be used to limit unnecessary contamination and to assure the overall safety of the water. Although they are not federally enforceable, EPA intends to publish National Secondary Regulations for these and other substances in the future based upon aesthetic considerations. The threshold for p-DCB appears to be in the range of 0.01 mg/l. The taste and odor threshold of 1,1,1-trichloroethane is about 1 mg/l.

D. Other Treatment Technologies

As stated in Section 1412(b)(6) of the Act, this regulation does not require the use of BAT (i.e., GAC or PTA), or any other technology to meet the MCLs; public water systems may use any appropriate technology acceptable to the State that treats all of the water and that results in compliance with the MCL. For example, there are many aeration technologies other than PTA (e.g., multiple tray aeration, diffused aeration, spray aeration) that remove VOCs and which a public water system may wish to install instead of BAT.

In the November 1985 notice, EPA proposed that point-of-use (POU) and plint of-entry (POE) technologies not be considered BTGA but be considered acceptable technology to meet MCLs, provided certain conditions were met (50 FR 46916, November 13, 1985). EPA dig not 9

propose POU or POE technologies as BTGA because of difficulties associated with monitoring compliance and assuring effective treatment performance in a manner comparable to cenitral treatment; furthermore, POU devices only treat the drinking water at a single tap. In add lition to potential exposure via ingestion at untreated taps, POU devices do not treat the exposture introduced through indoor air transport (e.g., from showers or dermal contact). In addition, these devices are generally not affordable by large metropolitan water systems, which is one of the criteria for setting BAT.

In the November 1985 notice, the Agency discussed its proposal to not allow PWSs to use bottled water for compliance or to meet conditions of variances and exemptions. Public comments pointed out that bottled water may, in a few cases, be the only available "treatment technique" for the the smallest systems. The Agency restated in its April 1987 notice that bottled water was not an acceptable means of meeting the MCL requirements on a permanent basis since it does not provide the same level of protection as central treatme int (i.e., persons may choose not to drink bottled water) and bottled water might allow significant exposure to water which does not meet the drinking water standard during showering and other applications. However, in that notice, EPA proposed that bottled watter be allowed as an interim measure to prevent an unreasonable risk to health during the timme between detection of an MCL violation and achievement of compliance; it is emphasized that provision of bottled water during this interim period does not bring the PWS into compliannce with the MCL; bottled water does, however, provide an acceptable source of water to drimk during the interim period. In a future notice, EPA will further assess the advisability of allowing some NTNCWS and very small systems to use bottled water to meet the MCL requirements.

The majority of commenters agreed that POU/POE devices and bottled water should not libe considered BAT, and that the NPDWR should not allow their use for compliance with MCLS, due to difficulties in controlling installation, maintenance, operation, repair, and potential human exposure via untreated taps. However, other commenters stated that POU/POE devices and bottled water should be considered BAT or allowed for compliance, as these technologies were often more cost-effective for some small systems than central treatme:nt.

In this final rule, POE and POU devices are not designated as BAT because: (1) It is significantly more difficult to monitor the reliability of treatment performance and to conterol the operation of POE and POU devices in a manner comparable to central treatment; (2) these devices are generally not affordable by large metropolitan water systems; and (3) in the case of POU devices, not all water is treated. In addition, under this rule, POU and boottled water are not considered acceptable means of compliance with MCLs. These devices do n lot treat all the water in the home and could result in health risks due to exposure to untreatted water. Consequently, POU devices and bottled water are only considered acceptable for unse as interim measures, e.g., as a condition of obtaining a variance or exemption, to avoid unreasonable risks to health before full compliance be be achieved. Under this rule, however, POE devices are acceptable means of compliance, because POE provides drinking water that meets the standards throughout the home. These devices may be cost-effective for small systems or nontransient non-community water systems (for which these devices would often be essentially the same as central treatment), although operational problems may be greater than for central treatment in a community system.

The SDWA requires EPA to establish necessary conditions for use of treatment that will assure protection of public health. Specifically, section 1401(I) of the Act states that primary drinking water regulations are to contain "criteria and procedures to assure a supply of drinking water which dependably complies with . . . maximum contaminant levels, including quality control and testing procedures to insure compliance with such levels and to insure proper operation and maintenance of the system." Accordingly, this rule impossible following conditions on those systems that use POE for compliance:

(1) Central Control. The public water system will be responsible for operating and 0 1 6 1 0

maintaining all parts of the treatment system (i.e., the treatment device). Central ownership is not necessary, as long as the public water system maintains control of the operation of the device. Central control is appropriate and necessary to ensure that the treatment device is kept in working order.

- (2) Effective Monitoring. As monitoring the quality of a PWS' drinking water is a central part of ensuring compliance with any NPDWR, the public water system must develop a plan and obtain State approval for a monitoring plan before it installs the POE devices. Because POE devices present a fundamentally different situation than central treatment, a unique monitoring plan must be developed. This monitoring plan must ensure that the POE devices provide health protection equivalent to central water treatment. Equivalent means that the water would meet all Primary and Secondary Drinking Water Standards and would be of acceptable quality similar to water distributed by a well operated central treatment plant. In addition to the VOCs, monitoring must include physical measurements and observations, such as total flow treated and the mechanical condition of the treatment equipment.
- (3) Application of Effective Technology. There are no generally accepted standards for the design and construction of POE devices, and there are a variety of POE designs available. Therefore, the State must require adequate certification of performance, field testing, and, if not included in the certification process, a rigorous engineering design review of each type of device. Certification can be done by the State or by a third party acceptable to the State.
- (4) Maintenance of the Microbiological Safety of the Water. The design and application of POE devices must consider the tendency for increases in bacterial concentrations in water treated with activated carbon and some other technologies. It may be necessary to use frequent backwashing, post-contactor disinfection, and monitoring to ensure that the microbiological safety of the water is not compromised. EPA considers this condition necessary because disinfection typically is not provided after point-of-entry treatment as is normal is used in a central treatment plant.
- (5) Protection of All Consumers. Every building connected to a public water system must have a POE device installed, maintained, and adequately monitored. If the building is sold, the rights and responsibilities of the utility customer must be transferred to the new owner with the title.
- E. Analytical Methods and Compliance Monitoring Requirements
- 1. Analytical Methods

In the November 1985 notice, the Agency proposed the use of three analytical methods that it considered economically and technologically feasible for monitoring compliance with the VOC MCLs. These methods were:

- (1) EPA Method 502.1, "Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography."
- (2) EPA Method 503.1, "Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography."
- (3) EPA Method 524.1, "Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography/Mass Spectrometry."

Capillary Column Techniques. Some commenters recommended the use of capillary column techniques for VOC analyses. The Agency evaluated capillary column methodology and agreed that they are available. Some commenters also recommended the use of detectors in series to analyze purgeable halocarbons and aromatics simultaneously. The Agency agrees 1 6 1 1 and has developed Method 502.2, which provides for the use of detectors in series, and

proposed capillary column analytical methods at <u>52 FR 12879</u> (April 17, 1987). This final rule includes the capillary column methods as approved analytical methods:

- (1) Method 524.2, "Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography/Mass Spectrometry."
- (2) Method 502.2, "Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography with Photoionization and Electrolytic Conductors in Series."

Disapproval of the 600 Series Methods. In addition, on May 27, 1986 (52 FR 19076), EPA requested comment on whether to approve the 600 series methods (i.e., EPA's analytical methods for detecting volatile synthetic organic compounds in wastewater, Methods 601, 602, and 624 in 40 CFR Part 136) for compliance monitoring since a number of comments to the November 1985 notice suggested they be approved as well.

EPA has evaluated the comments and determined that the 600 series methods are technically very similar to the 500 series methods (e.g., the analytes covered, and the analytical columns, detectors, and chromatographic conditions are the same). However, EPA has determined that the methods are not interchangeable for various reasons. First, their analytical objectives are different. The 500 series methods emphasize detectability at low levels while the 600 series methods do not focus on measurements near the MCLs (the sample volume is 5 ml in Method 624 versus 25 ml in Method 524.1). Second, the specific quality control requirements that must be met for the 500 series and the 600 series methods are different. The performance criteria specified in the 500 series methods are more stringent than those in the 600 series methods. For example, the 500 series methods include a requirement that laboratories analyze quality control standards within 60 and 140 percent of the expected value, while the established performance criteria of the 600 series methods, while they are different for each analyte, are wider. Therefore, EPA has not in cluded the 600 series methods in this regulation as acceptable analytical methods for compliance monitoring because these methods are not designed to maximize detectability at low levels and do not have as stringent performance criteria, as do the 500 series methods.

2. Compliance Monitoring Requirements

This final rule requires compliance monitoring to determine whether public water systems are distributing drinking water that meets the MCLs. The Agency has determined that the VOCs are Tier II contaminants in the three-tiered scheme presented in the Phase II Advance Notice of Proposed Rulemaking, published on October 5, 1983 (48 FR 45502), and further discussed in the November 13, 1985, VOCs MCL proposal (50 FR 46902). Tier II contaminants are those which are of sufficient concern to warrant national regulation (i.e., MCLs or treatment technique requirements) but which occur with limited frequency, therefore justifying flexible national minimum monitoring requirements to be applied by the State.

EPA presented three options in the November 1985 notice for VOC compliance monitoring requirements (50 FR 46919). EPA proposed option 2 for the reasons stated in that proposal. This option consisted of phasing in the monitoring requirements over a four-year period based on the size of the population served by the public water supply system. Specifically:

- (1) Ground-water systems would be required to take one sample per entry point to the distribution system. Surface water systems would sample at points representative of each source in the distribution system.
- (2) The initial sampling to determine compliance would consist of one sample every 3 months per source for a year for both surface and ground-water systems; the State would have the discretion to reduce the number of initial samples for ground-water systems if no VOCs were detected in that initial sample. Follow-up actions when VOCs are detected in that confirmation samples, would be left to the discretion of the State. Monitoring would be

phased in over four years with large systems first.

- (3) All systems would have to conduct repeat monitoring. The repeat monitoring frequency would be based on the initial monitoring results (i.e., whether VOCs were found) and on the vulnerability of the system to VOC contamination. EPA proposed a minimum repeat monitoring frequency of once every five years for systems not considered vulnerable based on the procedure established in the initial sample (i.e., each system samples once every 3 months for a year. If no VOCs are found and the system is not vulnerable to contamination, the State may reduce the sample to that taken in the first quarter. EPA also proposed that the State be required to confirm the vulnerability status of systems once a year).
- (4) Monitoring for vinyl chloride would only be required by ground-water systems detecting one or more chlorinated two-carbon VOCs (e.g., trichloroethylene, 1,2-dichloroethane, 1,1,1-trichloroethane, and 1,1-dichloroethylene) for the reasons detailed in the proposal (50 FR + 6919).
- (5) "Grandfathering" of previously collected data, of acceptable analytical quality (i.e., comparable to those laboratories that have interim certification), including sample analysis during Federal or State surveys, would be allowed for compliance monitoring purposes.

Appendix A to the November 1985 notice contained guidance for determining the vulnerability of public water systems to contamination by VOCs. The general criteria suggested were: (1) Population; (2) nearby use, storage, or disposal of VOCs; (e.g., proximity to landfills and RCRA sites); and (3) water source protection.

EPA encouraged the States and the PWSs to analyze their watersheds every three years by conducting a sanitary survey. EPA also encouraged systems to perform a comprehensive analysis to determine the presence of the eight VOCs proposed in the notice, the unregulated contaminants listed in this notice (in Section III.J), and as many as possible of the seventy-five other contaminants for which NPDWRs are to be promulgated by June 1989 as required by the SDWA. The State could use the results of this analysis, in part, to determine requirements for monitoring frequency for the eight VOCs.

EPA received a large number of comments on the proposed monitoring requirements. Most commenters supported the phase-in approach, as proposed. Other commenters stated that the costs of monitoring were too high and that the State should have even more discretion to determine which systems should monitor and how often. Some commenters recommended that consecutive water companies not be required to sample, that a monitoring exemption be allowed for small systems, and that EPA reduce the required sampling for systems with wells that only operate a few months a year. Other commenters recommended that the vulnerability assessment be included as part of the sanitary survey which is conducted every three years under the current NPDWR for coliforms, rather than annually. Commenters supported the provisions for "grandfathering" previous data in lieu of new data for the initial round of monitoring.

In this final regulation, EPA has retained the majority of the monitoring requirements described in the preferred option (Option 2). In the final regulation, EPA is requiring that all community water systems and NTNCWs conduct an initial round of monitoring to determine the extent of contamination of water supplies. All size systems must monitor as the occurrence data collected by EPA indicate that systems of all sizes have detected VOCs at relatively high concentrations, sometimes without apparent sources of contamination. In general, the likelihood of contamination increases with population, since areas of large commercial or industrial activity are often located in large population centers. The Ground Water Supply Survey of 1982 (Ref. 7) found that 16 percent of the smaller systems (<10,000 people) and 28 percent of the larger systems (>/=10,000 people) had detectable VOCs. EPA believes that phasing in the monitoring requirements by system size is reasonable because of the greater vulnerability of the large systems and because these systems can more easily

handle the monitoring costs associated with this regulation. In addition, phasing in the requirements over a four-year period will allow the analytical laboratories to develop the capability to handle the additional samples. This is consistent with previous regulatory actions implementing the Safe Drinking Water Act (eg., trihalomethanes).

EPA has modified the sampling locations for surface water systems such that samples can be taken after treatment from entry points to the distribution system taps that are representative of each source.

EPA investigated the feasibility of compositing samples for VOC analyses in an effort to reduce the monitoring costs. Sample-compositing could then be used as a screening test to determine whether samples from multiple sampling sites may be contaminated by VOCs. EPA investigated composites of 5 different samples since a concentration in the original sample above the PQL (and the MCL for some VOCs) should still be detectable but not quantifiable in a composite sample resulting from such dilution, for example, if one of the five samples were contaminated at 0.005 mg/l and the other four were zero. Reanalysis of each sample would be required if VOCs were detected in the composite sample. The experiments conducted by EPA were done to determine whether sample-compositing would work for the VOCs (i.e., whether VOC losses could be kept to a minimum), and to determine the technique most appropriate to minimize VOC losses.

The experiments conducted involved the preparation of composite samples for GC and GC/MS analyses. The procedures investigated for each type of analysis were different because of the difference in sample size (5-ml sample purged for GC analyses; 25-ml sample for GC-MS analyses). The compositing technique that worked best for GC analyses involved the addition of five 5-ml samples to a 25-ml glass syringe and, after mixing, drawing out a 5-ml aliquot for analysis. The mixing should be done with the sample cooled at 4 deg. C to minimize VOC losses. Data collected for five replicate samples demonstrated excellent recovery for all compounds (95-100 percent) with good precision, generally 3-5 percent relative standard deviation. The recommended compositing technique for GC/MS analyses involves the injection of 5 ml of each sample directly into the purge device. For most components, recoveries were greater than 85 percent with good precision, generally between 3-5 percent relative standard deviation (Reference 1).

Based on this information, procedures for compositing samples are included in the regulations. Several points are briefly addressed below. Samples are to be collected from each source and shipped to the laboratory where they will be composited. Compositing is not done in the field. Public water systems and States that collect samples must be aware that there are some potential problems that should be kept in mind when they composite samples. It is desirable that sampling schedules be arranged in a manner that provides for collection of all samples to be composited the same day. Sample preparation and analysis must take place within the maximum holding time of 14 days. The samples collected are shipped to the laboratory where the analyst will prepare a composite sample from a series of discrete samples. This additional sample preparation step provides more opportunity for the introduction of recordkeeping errors so additional care must be taken. EPA recommends that all samples be collected in duplicate to provide an additional sample in case VOCs are detected in the composite sample. This would avoid the need to resample at each sample site to determine which site(s) may be contaminated. If VOCs are detected in the composite sample, the original samples cannot be reanalyzed because of head space problems created when the first aliquot was taken. Reanalysis must be conducted for each of the duplicate samples, provided the maximum storage time of 14 days has not been exceeded. Resampling must be done immediately where one or more VOCs are detected if no duplicates are available.

The greatest limitation of compositing samples from different sources is that the analytical results will not actually provide a measurement of what is in the wat for the composite sample turns out to be negative. It is possible that some VOCs may be present at trace levels

and will not be detected in a composite sample. Therefore, sample-compositing is not the preferred approach but one that can be used when monitoring costs add a significant economic burden, with recognition of its limitations.

Confirmation samples of positive results can be required by the State; results of confirmation samples must be included in the quarterly average along with the initial sample. States, however, have discretion to delete obvious analytical errors in the initial or confirmation samples. In addition, States have discretion to require additional monitoring samples; results of all samples must be included in each respective quarterly average (except as noted above for obvious errors).

EPA modified some of the monitoring requirements it proposed in the November 1985 notice to address the concern of many commenters regarding monitoring costs. These changes are summarized below and further discussed in the Methods and Monitoring document (Ref. 1).

- (1) The number of samples required for ground and surface water systems has been reduced from the number proposed. The rule allows composite samples of multiple sampling sites (up to five samples), resulting in lower costs. When monitoring costs would create an unacceptable financial burden, States that conduct the monitoring themselves can composite samples from different systems. This may be particularly beneficial for monitoring non-transient non-community water systems. As proposed, under the final rule, if VOCs are detected in a composite sample, follow-up analysis is required for each source (see discussion of composite samples).
- (2) The repeat compliance monitoring requirements for those systems that the State determines are vulnerable but in which no VOCs were found in the initial sample, are based upon system size (see Table 4).
- (3) For systems finding two-carbon VOCs, vinyl chloride analysis is required. If vinyl chloride is not detected in the initial sample States can reduce monitoring frequencies to once every three years for vinyl chloride.

As for comments recommending that EPA reduce sampling for systems with wells that only operate a few months a year, the Agency believes that any such reduction is appropriate. Under this final rule monitoring is required for all wells, including backup wells, only when they are being used. For example, four quarterly samples would not be required for wells that are only used for say two months per year; however, a sample each quarter that the wells operate would be needed.

The Agency agrees with the recommendation that the State make a vulnerability assessment once every three years rather than every year as proposed. In addition, EPA believes that the State should make a vulnerability assessment (</=500 connections) every five years only. These changes are reasonable because it is unlikely that significant undetected changes would occur in the vulnerability of a system sufficient to result in sufficient VOC contamination within a one- to two-year time period. The final rule reflects these changes.

EPA also proposed the following method for determining compliance:

- (1) All quarterly compliance samples would be collected on the same day and analyzed according to procedures promulgated in this rule.
- (2) Compliance with the MCL would be computed by running arithmetical average of the past four quarterly samples.
- (3) Compliance would be determined for each sampling location; if water at that location was above the MCL, the entire system would be deemed out of compliance and public notice would be sent to all customers served by the system unless there was the inter-mixing of

source waters in distribution.

EPA received a number of comments on the proposed method of determining compliance. Many commenters supported the methods, while other commenters believed that only that portion of the system exceeding the MCL should be considered out of compliance and that public notification should be limited to the affected consumers. EPA believes that it is often not possible to determine the specific subpopulation of consumers receiving water from a specific part of a water system, due to mixing of waters and changes in water feed pattern. However, it is recognized that certain systems may have a clearly definable distribution system from a source with no interconnections to any other source. To accommodate these different situations, EPA is promulgating the requirements for determining compliance and public notification as proposed, except that the State may determine that only one segment, i.e., the affected part of a public water system, is out of compliance and limit public notification to that one segment.

EPA received a number of comments suggesting that monitoring data from further back than the proposed three years be allowed in the "grandfather" provision. Since the 1986 Amendments to the SDWA allow use of data for unregulated contaminants back to January 1, 1983, EPA feels it appropriate to allow States discretion to also use monitoring data for the 8 VOCs back to that date. If a system is judged to be not vulnerable, the previous monitoring data can be used to represent the first round of monitoring. In addition, States can use the results of EPA's Ground Water Supply Survey for systems with single sources in the same manner; only single sources are appropriate because EPA sampled from points in the distribution system during the survey.

In conclusion, the final monitoring requirements for determination of compliance with the VOC MCLs are as follows:

(1) All CWS and NTNCW systems must monitor every three months for a year. The running average will determine compliance. If a system is not classified as "vulnerable" and the first quarterly sample does not detect VOCs, the State may waive the requirement for additional sampling.

The State may also reduce the total number of samples by the use of composite samples of multiple entry points (up to five entry points per sample) if the composites reflect operating characteristics. If VOCs are detected in a composite, follow-up sampling is required at each entry point included in the composite. This requirement will be phased in based on the size of the population served by the system as follows:

Begin no later

System size	than			
>10,000	Jan.	1,	1988.	
3,300 to 10,000	Jan.	1,	1989.	
<3,300	Jan.	1,	1991.	

- (2) Ground-water systems must sample at each entry point which is located after any treatment to the distribution system every three months.
- (3) Surface water systems may sample at points in the distribution system that are representative of each source or at each entry point to the distribution system which is located after any treatment. The minimum number of samples is one sample per source, per quarter for one year. Composite samples representative of up to five sources are allowed. If VOCs are detected in the first or any subsequent sample, follow-up manitoring is required as specified by the State.

- (4) Additional samples, when required by the State, are to be taken at each entry point that was included in the composite sample. If it is possible to determine from the follow-up samples which entry point(s) is out of compliance, then only that entry point(s) need be sampled unless the State determines that other entry points are vulnerable.
- (5) Monitoring for vinyl chloride is required only for ground water systems which detect another chlorinated two-carbon VOC (trichloroethylene, 1,2-dichloroethane, 1,1,1,-trichloroethane, 1,1-dischloroethylene, tetrachloroethylene, cis-1, 2-dichloroethylene, or trans-1, 2-dichloroethylene).
- (6) All systems to which the regulations apply are required to conduct repeat monitoring except for surface water systems that the State has not classified as vulnerable and did not detect any VOCs in the first round of sampling. The frequency of such monitoring will be based on prior monitoring results, the volunerability of the system, and for those cases where VOCs have not been detected but the system is vulnerable, by system size.
- (7) These requirements are summarized in the table below:

TABLE 3. -- SCHEDULE OF REPEAT MONITORING REQUIREMENTS

Status	Ground water	Surface water n1		
VOCs are not detected * in the	Repeat at least	State discretion.		
first or any subsequent sample	every 5 years			
and the system is not vulnera-				
ble.				
VOCs are not detected and				
system is vulnerable:	·			
Systems >500 connections	Repeat every 3 years	Repeat every 3 years.		
Systems =500 connections</td <td>Repeat every 5 years</td> <td>Repeat every 5 years.</td>	Repeat every 5 years	Repeat every 5 years.		
VOCs detected in any sample	Quarterly	Quarterly.		

- n1 Must sample for four consecutive quarters.
- * Detected is 0.0005 mg/l.
- (8) States must certify the vulnerability status of systems at least every three years (five years for smaller systems (i.e., </=500 connections).
- (9) States have the discretion to: Require confirmation samples for positive results,

Reduce the repeat monitoring requirements for systems detecting VOCs, but at levels consistently less than the MCL, from quarterly sampling to no less than annual sampling after a baseline of data is developed during at least a three-year period,

Allow the use of monitoring data collected after January 1, 1983, in lieu of new data for the first sample if the data are of an acceptable quality and will provide information equivalent to that required in the rule.

(10) Compliance with the MCL will be based upon a running annual average of quarterly samples for each sampling location (i.e., the previous four quarterly samples). If the annual average for any sampling location is above the MCL, the system is out of compliance, public notification of the system's customers is required.

If any one quarterly sample would cause the annual average to be exceeded, the system is out of compliance as of that quarter. For example, if the first quarterly cample exceeded four

times the MCL, the system would be out of compliance. The intent of this provision is to provide early notification of potential health risks.

If the State reduces the monitoring to one sample, the compliance determination is based upon that one sample.

F. Laboratory Approval

EPA's existing rules in 40 CFR 141.28 require that analyses for compliance monitoring purposes be conducted only by State-approved laboratories. Laboratories wishing to obtain approval for conducting VOC analyses must successfully analyze performance evaluation samples within the limits established by EPA and meet other requirements. The acceptance limits for laboratory approval are derived from the performance evaluation study data, i.e., the Water Supply Study series.

EPA requested comment on the use of a "plus or minus percent of true value" approach for setting performance criteria (i.e., acceptance limits). Most commenters supported the use of a "plus or minus percent" approach to derive acceptance limits over generating them from study statistics based upon 95 percent confidence limits. Some commenters believed, however, that the specific acceptance limits proposed were too strict and there would be an insufficient number of laboratories available that could meet such standards. EPA disagrees with this comment because the most recent water supply performance evaluation study showed that about 85 percent of all data submitted to EPA and State laboratories and about 70 percent of the other participating laboratories were within the proposed acceptance limits. These results compare favorable with other regulated contaminants where, even after years of experience, only 80-85 percent of all the data submitted are within the acceptance limits for each study. A specific example is the trihalomethanes, where about 85 percent of the data submitted by EPA and State laboratories and about 75 percent of the data submitted by other participating laboratories are within the established limits. The actual percentage varies somewhat from study to study.

The acceptance limits were proposed to be +/-40 percent of the true value for concentrations less than 0.010 mg/l, and +/-20 percent of the true value for concentrations of 0.010 mg/l or above for all of the VOCs except vinyl chloride. More recently, data from Water Supply Study No. 17, at 51 FR 19077 (May 27, 1986) indicate that most of the better laboratories tested can successfully analyze performance evaluation within the proposed acceptance limits. EPA considered lowering the acceptance limits for the seven VOCs to +/-20 percent (excluding vinyl chloride). However, very few laboratories would be able to perform within these limits for all seven of the VOCs. Only three out of eighteen laboratories were able to analyze six out of seven VOCs within these limits in Water Supply Study #17. Therefore, in the final rule, the acceptance levels are +/-20 percent of the true value for concentrations of 0.010 mg/l or above, and +/-40 percent of the true value for concentrations below 0.010 mg/l for seven VOCs (trichloroethylene, carbon tetrachloride, 1,1,1-trichloroethane, 1,2-dichloroethane, benzene, 1,1-dichloroethylene, and p-dichlorobenzene).

For vinyl chloride, the final acceptance limits are based initially on +/-40 percent of the true value at all levels. This is because the available data support acceptance limits of \pm /-40 percent and do not support acceptance limits of +/-20 percent for this compound. EPA may modify the laboratory performance requirements for all VOCs as new information becomes available.

Even the best laboratories may not be able to analyze all the VOCs within the acceptance limits 100 percent of the time. Random errors are likely to occur in any large data generation activity. EPA has evaluated data from recent performance evaluation studies to determine how many analytes EPA and State laboratories were able to analyze within the acceptance limits. The number of analytes within the acceptance limits varies from to laboratory. EPA evaluated data from Water Supply Study #17 for EPA and State laboratories

that analyzed for all eight VOCs. The data indicate that 15 out of 18 laboratories (or 83 percent of the laboratories) were able to analyze at least 6 out of 7 VOCs (excluding vinyl chloride) at concentrations of 0.004 mg/l or above within the acceptance limits, while only 7 of these laboratories (or 39 percent of the laboratories) were able to analyze all 7 VOCs. For very low levels (<0.004 mg/l) greater failure rates would result. When the highest concentration of p-dichlorobenzene (0.776 mg/l) was not considered, 15 laboratories were still able to analyze at least 6 out of 7 VOCs within the acceptance limits, while the number of laboratories that were able to analyze all 7 VOCs increased to 12 (or 67 percent of the laboratories). For vinyl chloride only 8 out of 18 laboratories (or 44 percent of the laboratories) were able to analyze all three levels within the +/-40 percent acceptance limits. When the lowest concentration (0.0015 mg/l) was not considered, the number of laboratories within the acceptance limits increased to 13 out of 18 (or 72 percent of the laboratories).

EPA also evaluated preliminary data from Water Supply Study #20 to determine whether this study supports the results from the Water Supply Study #17. Two samples were offered in this study to those laboratories wishing to obtain conditional approval for VOCs. One sample contained the eight VOCs for which MCLs are being set in this notice. The second sample contained 4 of the 8 VOCs plus other Section 1445 unregulated VOCs. Excluding vinyl chloride, there were a total of 11 responses for the 7 VOCs (7 from the first sample and 4 from the second sample). The results are summarized in Table 4 for a total of 44 EPA and State laboratories.

TABLE 4. -- ANALYSES WITHIN

THE ACCEPTANCE

LIMITS OF ELEVEN VOC SAMPLES

	Num-	Per-	
	ber of	cent of	
	labora-	labora-	
Acceptable data	tories	tories	
11 out of 11	8	18	
10 out of 11	22	50	
9 out of 11	31	70	
8 out of 11	36	82	
<8 out of 11	8	18	

Taking the data from the first sample for the seven VOCs, 36 out of 44 laboratories (or 82 percent of the laboratories) were able to analyze at least 6 out of 7 VOCs within the acceptance limits, while only 22 out of 44 (or 50 percent of the laboratories) were able to analyze all seven VOCs. These results are similar to the results obtained in Water Supply Study #17 for the 7 VOCs.

Twenty-nine out of the 44 laboratories (or 66 percent of the laboratories) were able to analyze vinyl chloride within the \pm -40 percent limits. These results are similar to the results obtained in Water Supply Study #17 when the lowest concentration (0.0015 mg/l) was not considered.

Based on the results obtained in Water Supply Study #17 (which are supported by preliminary results from Water Supply Study #20), EPA concluded that it is reasonable to expect that laboratories meet the acceptance limits in § 141.24(g)(11) for at least 6 out of 7 of the VOCs to receive conditional approval. Therefore, the Agency will provide conditional approval of VOC analysis to laboratories that meet the following requirements:

(1) Use approved analytical methods as specified in §§ 141.24(g)(10) and 1(1444);

- (2) Are approved for THMs analysis; and
- (3) Perform within the acceptance limits for at least 6 of the 7 VOCs (excluding vinyl chloride).

In addition, special conditional approval will be granted separately to laboratories wishing to analyze for vinyl chloride if they meet (1) and (2) above, and are able to perform within the acceptance limits for vinyl chloride at all levels.

The above performance criteria apply specifically to laboratories that participated in Water Supply Study #20. These requirements will apply to conditional approval until such a time when EPA evaluates additional Water Supply Study data and develops final certification criteria. States that provide their own performance evaluation samples instead of EPA samples must use testing procedures equivalent to Water Supply Study #20 and must apply the same requirements, as described above, to grant conditional approval to laboratories.

G. Variances and Exemptions

1. Variances

The conditions for granting a variance from an NPDWR are specified in Section 1415(a)(1)(A)of the Safe Drinking Water Act. According to this provision of the ACT, EPA or a state which has primary enforcement responsibility (i.e., the primacy agent) may grant variances from MCLs to those public water systems that cannot comply with the MCLs because of characteristics of the water sources that are reasonably available. A variance may only be granted to those systems which have installed best available technology, treatment techniques, or other means which EPA finds are available (taking cost into consideration); in this notice these treatment techniques will be referred to collectively as BAT. Furthermore, before a State may grant a variance, it must find that the variance will not result in an unreasonable risk to health. The level representing unreasonable risk to health for each of the VOCs will be addressed in the proposal addressing the next 40 contaminants required to be regulated under the SDWA by June 1988. The proposal is scheduled for the Fall of 1987. In general, the unreasonable risk to health level would reflect acute and subchronic toxicity for shorter-term exposures and high carcinogenic risks (as calculated using the linearized multistage model in accordance with the Agency's risk assessment guidelines) for long-term exposures.

Under Section 1413(a)(4), States that choose to issue variances must do so under conditions, and in a manner, which are no less stringent than EPA allows in Section 1415. Of course, a State may adopt standards which are more stringent than the EPA standards.

Best Available Technologies for Variances. In the November 1985 notice, EPA proposed two technologies as the best technologies generally available (BTGA) for the treatment of VOCs: packed tower aeration (PTA) and granular activated carbon (GAC). The public comments that EPA received supported this finding. The 1986 amendments to the SDWA changed the technology standard for drinking water treatment from BTGA to best available technology (BAT). After carefully reexamining the proposed rule in light of the 1986 amendments, the Agency has decided that packed tower aeration or granular activated carbon are also BAT for variance purposes (except for vinyl chloride, for which BAT is only packed tower aeration); this decision is based upon the factors discussed in Section II of today's preamble.

Under Section 1415(a)(1)(A), EPA's determination of BAT for variances may vary from BAT for setting MCLs under Section 1412 based on the number of persons served by a particular water system, the physical conditions related to engineering feasibility, and the costs of compliance. With respect to small systems, there are no engineering aspects of these two technologies which would indicate that EPA should specify different BATs for variances, since VOC removal rates, operational feasibility, and equipment availability do not apprent

application to even the smallest systems. In fact, both technologies are currently commercially available in sizes that can treat a single home, a few (e.g., 15) homes, or larger size systems. Therefore, EPA has determined that its selection of packed tower aeration and granular activated carbon as BAT need not be varied due to system size, or physical characteristics, and that these technologies are BAT for all public water systems.

Costs Considerations in Applying BAT to Small Systems. The Agency based its decision to designate packed tower aeration and granular activated carbon as BAT under Section 1415 for all size systems in part on the following analysis of small system costs. Table 3 displays the costs of 99 percent removals of the eight VOCs for the smallest system size (25-100 persons or 13,000 gallons per day) using PTA or GAC. (See Ref. 2 for a more detailed discussion.) The costs of treatment for the very small size category (25-100 persons or 13,000 gallons per day) range from 70 cents per thousand gallons for removal of trichloroethylene by GAC to 204 cents per thousand gallons for removal of paradichlorobenzene by PTA. On an annual basis, this might increase the average small system residential water bill by about \$70 per year to remove trichloroethylene and \$200 per year to remove 1,2-dichloroethane.

GAC

TABLE 5. -- ESTIMATED COSTS OF REMOVING VOCS FROM

DRINKING WATER

PTA

USING PACKED TOWER AERATION OR GRANULAR ACTIVATED

CARBON FOR

THE SMALLEST SYSTEM SIZE *

[Assuming 99 percent removal from $0.5~\mathrm{mg}/1$ to $0.005~\mathrm{mg}/1$]

c/			_			c/
Annual 1,000		*	Annual			1,000
Chemical	Capital	O & M	gallons	Capital	O & M	gallons
TCE	\$58,000	\$800	169	\$13,000	\$1,600	70
C. Tet	52,000	700	162	13,000	2,000	79
1,2-DCA	62,000	1,300	202	13,000	330	106
V.C.	48,000	600	148	NА	NA	NA
1,1-DCE	50,000	600	154	13,000	1,600	70
Benzene	56,000	1,000	180	13,000	5,500	153
1,1,1-TCA	50,000	700	156	13,000	3,500	110
p-DCB	63,000	1,300	204	13,000	1,700	72

^{*} Cost are in 1983 dollars. Smallest system = 13,000 gallons/day average flow or 25-100 persons served.

Although current total water costs for typical small system households range from about \$100 to \$150 per year, these costs are quite low in comparison to the costs of other utilities. In addition, as system size increases, the costs of water treatment per unit volume of water rapidly decline. For example, using all the same assumptions, the packed tower aeration costs decrease from 202 cents per thousand gallons for the 25 to 100 person (0.013 mgd) system size category to 101 cents per thousand gallons for the 101 to 500 person (0.037 mgd) system size category, and decrease further to 21 cents per thousand gallons for the 50,001 to 75,000 person (12 mgd) category. Thus, aeration treatment offers significant economies of scale, e.g., with respect to 1,2-dichloroethane removal, as plant size increases by a factor of three (0.013 mgd to 0.037 mgd), the cost decreases by a factor of two (202 to 101¢/1,000 gallons). In addition, costs will be less when lower removal efficiencies are sufficient to achieve the standard in those cases where the raw water concentrations are less than 0.5 mg/1, which is usually the case.

It should be noted that the costs in Table 3 are based on a variety of data (see Ref. 2). For all the VOCs, except vinyl chloride, benzene, and p-dichlorobenzene, carbon usage rates are based on projection of pilot column data. Neither adequate adsorption isotherms nor column data were available to project carbon usage rates or empty bed contact times for vinyl chloride. As indicated earlier, GAC adsorption is not considered BAT for the removal of vinyl chloride because of this and other feasibility considerations. For the two aromatic compounds, benzene and p-dichlorobenzene, only carbon adsorption isotherms were available. That is, no pilot column data were available for these two compounds. To compensate for this lack of pilot column data, the cost estimates in Table 3 for these two compounds were adjusted to be higher than if column data had been available (see Ref. 2). These costs are believed to be adequate for purposes of determining MCLs and estimating national economic impacts.

Both pilot- and full-scale data demonstrate that packed tower aeration and granular activated carbon are capable of 90-99 percent or greater removals of the VOCs (except that GAC is not as effective as PTA for vinyl chloride). In light of this removal efficiency and the potential cost impacts, the Agency considers the treatment costs to be justified and reasonable; under a worst case scenario, the water rate might double for the smallest system consumers. Consequently, the Agency has concluded that there is no reason to vary the BAT standard for small systems.

Required Examination and Installation of Alternate Treatment Technologies. Under section 1415 of the Act, a State may grant variances from a NPDWR if certain conditions are met. These conditions, described more fully below, include: (1) An inability to meet the MCLs despite the installation of the best available technology; (2) a finding that the variance will not result in an unreasonable risk; (3) imposition of a compliance schedule; (4) implementation of such additional control measures as the State may require; and, (5) public notice of the proposed variance and opportunity for a hearing.

To receive a variance, a PWS would be required to install BAT first even if the BAT was not anticipated to achieve the MCL; the objective would be to reduce the level of contaminants as much as could be achieved by those technologies. The only exception to this requirement is that if a system were to demonstrate that the best available technology only achieved de minimis reduction of the contaminant(s) of concern, the system would not have to install that technology. However, as a condition of receiving a variance without installing BAT, the State could require comprehensive engineering studies of other technologies and if any were technically feasible, it could require one of those technologies to be installed.

EPA has identified three additional treatment methods that the State may require the PWS to investigate and, if feasible, to install as a condition of obtaining a variance. These are: (1) Removal using other aeration techniques, such as multiple tray aeration, spray aeration, cascade aeration, diffused aeration, or mechnical aeration; (2) removal using powdered activated carbon adsorption; and (3) use of an alternative source of water.

EPA discourages systems from using an alternative source of water which has no VOC contamination but may be contaminated with other substances. Specifically, EPA discourages systems which find low levels of VOCs in their ground water source, which is otherwise of good quality, from switching to a surface water source where the risk from disinfection byproducts (e.g., trihalomethanes) might be greater than from the VOCs. In such a case, where alternative sources pose a greater risk than the VOC-contaminated supply, the water supplier should treat the original water.

Subsections 1415(a)(1)(A) (i) and (ii) of the SDWA require the State to prescribe a schedule for compliance at the same time that it issues a variance. The schedule must include: (1) Increments of progress toward compliance; and (2) an implementation plan of such control measures and application of other treatment techniques or technologies that W State considers necessary. These provisions are aimed at bringing the system into compliance with

the MCL as soon as practicable. The following points need to be taken into consideration:

- (1) The schedule of compliance which accompanies a variance may require that the system examine other treatment methods (e.g., various aeration technologies, powdered activated carbon, or alternate sources of water) to determine their availability, feasibility, costs, and effectiveness.
- (2) Such an examination may include engineering studies and pilot projects, for potentially applicable technologies, to determine what reduction in VOC levels could be achieved by the treatment method. EPA will provide guidance on examining technologies for compliance schedules.
- (3) Systems or the State always have the option of proposing studies of other methods.
- (4) The State can decide whether any of the possible teatment methods would achieve reductions in VOC levels justifying use of that particular method. In such cases, the State may require, as part of the compliance schedule, installation and use of such methods by the system.

Use of POU Devices and Bottled Water. As described above, under section 1415(a)(1)(A)(ii), the State is to prescribe a schedule for implementation of any additional control measures it may require. The State may require the use of POU devices, bottled water, or other mitigating measures as an "additional control measure" during the period of a variance, as a condition of receiving the variance, if an unreasonable risk to health exists.

In prescribing the use of POU devices, the State would be required to impose the same conditions as outlined in section III.A.1 for approval of POE devices. If a PWS distributes bottled water as a control measure, the PWS must ensure that the following conditions are satisfied:

- (1)(a) The bottled water is subject to a monitoring program that provides adequate assurances that the water meets all MCLs. The public water system must monitor the bottled water for VOCs the first quarter that it supplies water to the public, and annually thereafter. Results of the monitoring program shall be provided to the State annually, or
- (b) The public water system must receive a certification from the bottled water company that (i) the bottled water supplied has been taken from an "approved source" as defined in 21 CFR 129.3(a); (ii) the bottled water company has conducted monitoring in accordance with 21 CFR 129.80(g) (1)-(3); and (iii) the bottled water does not exceed the MCLs or quality limits set out in 21 CFR 103.35. The public water system shall provide the certification to the State the first quarter after it supplies bottled water and annually thereafter; and
- (2) The public water system is fully responsible for the provision of sufficient quantities of bottled water to every person supplied by the public water system including delivery via a door-to-door bottled water delivery system.

These conditions constitute the minimum standards for protection of public health.

2. Exemptions

Under section 1416(a), a State may exempt public water systems from any requirements respecting an MCL or treatment technique requirements of an NPDWR, if it finds that (1) due to compelling factors (which may include economic factors), the PWS is unable to comply with the requirement; (2) the exemption will not result in an unreasonable risk to human health; and (3) the PWS was in operation on the effective date of the NPDWR, or for a system which was not in operation by that date, only if no reasonable alternative our of drinking water is available to the new system. If a State grants an exemption to a public water

system, it must at the same time prescribe a schedule for compliance (including increments of progress) and implementation of appropriate control measures that the State requires the system to meet while the exemption is in effect. Under section 1416(2)(A), the schedule must require compliance within one year after the date of issuance of the exemption. However, section 1416(b)(2)(B) states that the State may extend the final date for compliance provided in any schedule for a period not to exceed three years, if the public water system is taking all practicable steps to meet the standard and one of the following conditions applies: (1) The system cannot meet the standard without capital improvements which cannot be completed within the period of the exemption; (2) in the case of a system which needs financial assistance for the necessary implementation, the system has entered into an agreement to obtain financial assistance; or (3) the system has entered into an enforceable agreement to become part of a regional public water system. For public water systems which do not serve more than 500 service connections and which need financial assistance for the necessary improvements, the State may renew an exemption for one or more additional two-year periods if the system establishes that it is taking all practicable steps to meet the requirements noted above. Section 1416(b)(2)C).

Under section 1416(d), EPA is required to review State-issued exemptions at least every three years and, if the Administrator finds that a State has, in a substantial number of instances, abused its discretion in granting exemptions or failed to prescribe schedules in accordance with the statute after following various procedures, the Administrator may revoke or modify those exemptions and schedules. EPA will use these procedures to strictly scrutinize exemptions from the MCLs for VOCs granted by states and, if appropriate, will revoke or modify exemptions granted.

Under this rule, as a condition of receiving an exemption, the State may require the use of POU devices or bottled water for the duration of the exemption. The conditions for the use of POU devices or bottled water are the same as those described for variances in section III.G.1.

3. Central Treatment vs. POU/Bottled Water

EPA believes that, when treatment is appropriate, central treatment should be the primary means of attaining MCLs. However, although the long-term goal for these systems is to meet MCLs with centrally treated and distributed water, EPA is allowing the State to require the use of POU devices or bottled water, for instance, if there is an unreasonble risk to health, as a condition of receiving a variance or an exemption to ensure that the PWS provides an interim source of drinking water that meets the MCLs while the system brings its water supply into compliance. This is especially valuable in the case of exemptions for small systems, i.e., systems with less than 500 connections, because their exemptions may be extended for one or more two-year periods. The goal is application of non-central treatment or bottled water is to provide water of equivalent quality to that which would be provided by a traditional well operated central treatment facility. Equivalent means water that meets all Primary and Secondary Drinking Water Standards and is not an acceptable quality.

H. Public Notification

Under section 1414(c)(1) of the Act, each owner or operator of a public water system must give notice to persons served by it of (1) any violation of any MCL, treatment technique requirement, or testing provision prescribed by an NPDWR; (2) failure to comply with any monitoring requirement under section 1445(a) of the Act; (3) existence of a variance or exemption; and (4) failure to comply with the requirements of a schedule prescribed pursuant to a variance or exemption. The 1986 amendments require that, within 15 months of enactment, EPA amend its current public notification regulations to provide for different types and frequencies of notice based on the differences between violations which are intermittent or infrequent and violations which are continuous or frequent acking into account the seriousness of any potential adverse health effects which may be involved.

EPA proposed regulations to revise the public notification requirements on April 6, 1987 (52 FR 10972). The regulations proposed that public notices for MCL and treatment technique violations ("Tier 1 violations") contain mandatory health effects language specifying concisely and in non-technical terms what adverse health effects may occur as a result of the violation. States and water utilities would remain free to add additional information to each notice, as deemed appropriate for specific situations. The April 1987 notice proposed specific health effects language for the eight VOCs which are subject to today's rulemaking. The April 1987 notice also proposed that a CWS with Tier 1 violations must notify the public by newspaper, mail delivery of notice and press release (for acute violations) is required. The proposal states that public water systems which fail to comply with any monitoring or testing requirements, which are granted variances or exemptions, or which fail to comply with the requirements of a variance or exemption schedule, would be required to give newspaper notice, with additional notice at State discretion. The PWS is allowed to post notice under certain conditions for Tier 1 and Tier 2 violations. The Agency expects to promulgate final public notification regulations in September 1987.

I. Reporting Requirements

The current regulations, 40 CFR 141.31, require public water systems to report monitoring data to States within specified time periods. EPA did not propose any changes in these requirements for the VOCs. No comments were received on this issue. Thus, EPA will require the same reporting requirements for the VOCs as required under the current regulations for other contaminants.

The reporting requirements for results of the monitoring for unregulated contaminants (described below) apply to both the community water systems (CWS) and the NTNCWS. Eac:h CWS or NTNCWS must submit the results of the monitoring within thirty days of receipt from the certified laboratory. These results are to be submitted to the State. In addition, the Statee or public water system must submit the following information to EPA for every sample: (1) Results of all the analytical methods, including negatives; (2) name and address of the system that supplied the sample; (3) contaminants for which the analyses were performed; (4) analytical method(s) used; (5) date of sample; and (6) date of analysis.

J. Total Volatile Synthetic Organic Chemicals (TVOC)

In the June 12, 1984, proposal for MCLGs for the VOCs, EPA requested public comments on setting an MCLG and MCL for total volatile organic chemicals to provide additional protections from simultaneous exposure to multiple VOCs. Following analysis of public comments and available scientific information, EPA determined that an MCLG and MCL would not be appropriate at this time. This conclusion was discussed in the November 1985 notice.

K. Monitoring for Unregulated Contaminants

Section 1445(a)(1) of the Act requires EPA to promulgate regulations by December 19, 19817, which require public water systems to conduct a monitoring program for unregulated contaminants. Each system must monitor at least once every five years for unregulated contaminants unless EPA requires more frequent monitoring. This data will assist EPA in determining whether regulations for these contaminants are necessary, and if so, what levells might be appropriate.

EPA proposed monitoring requirements for 51 unregulated contaminants in the November 1985 notice. The Agency also requested comment on a method developed for the analysis of 1,2-dibromoethane (EDB) and 1,2-dibromo-3-chloropropane (DBCP) at low levels. These two compounds are included among the substances that PWSs must monitor under Section 144.5, as discussed below. This method is entitled "Method 504 -- 1,2-Dibromoethane (EDB) and 1,2-Dibromo-3-chloropropane in Water by Microextraction and Gas Chromatography." EPA

received no comments on Method 504. The Agency believes that this method is adequate to determine concentrations of EDB and DBCP. Therefore, this method is included in this rule as the monitoring method for these two contaminants. Several commenters pointed out that analysis of 10 to 15 other compounds on the list of 51 was more difficult than analysis of the other compounds, resulting in higher costs. In addition, they observed that the likelihood of these substances being present is much less than for other VOCs. EPA agrees with these comments and thus is promulgating monitoring regulations which separate the unregulated contaminants into three lists as follows:

List 1: Monitoring required for all CWS and NTNCWSs. Compounds can be readily analyzed.

List 2: Monitoring required only for systems vulnerable to contamination by these compounds. Compounds have limited localized occurrence potential and require some specialized handling.

List 3: The State decides which systems would have to analyze for these contamin ants, which includes compounds that do not elute within reasonable retention time using packed column methods or are difficult to analyze because of high volatility or instability, and are much less likely to be present in drinking water.

EPA is deleting the monitoring requirements for pentachloroethane and bis(2-chloroisopropyl) ether from the list of unregulated contaminants in the final rule. Pentachloroethane has been deleted because it is unstable in water. Bis(2-choroisopropyl) ether has been deleted because it does not purge well, and there are very few occurrences in drinking water. Therefore, both of these are low priority compounds for regulation. EPA is adding tetrachloroethylene to List 1 because the rulemaking for this contaminant is now included with the contaminants scheduled for regulation in June 1988 and the resulting monitoring data will be useful (see the November 13, 1985, notice for discussion of the tetrachloroethylene regulation). In addition, 1,3-dichloropropene has been added to List 1 because it has been detected in ground waters and is measured by these analytical methods. Data gathered under this Section 1445 regulation can be used for compliance purposes when EPA promulgates regulations for tetrachloroethylene and any other of these VOCs for which EPA is developing MCLs.

Table 6 presents the three lists of compounds.

Table 6 -- Unregulated Contaminants

List 1: Monitoring Required for All Systems

Bromobenzene

Bromodichloromethane

Bromoform

Bromomethane

Chlorobenzene

Chlorodibromomethane

Chloroethane

Chloroform

Chloromethane

- o-Chlorotoluene
- p-Chlorotoluene

Dibromomethane

- m-Dichlorobenzene
- o-Dichlorobenzene

trans-1,2-Dichloroethylene

cis-1,2-Dichloroethylene

Dichloromethane

- 1,1-Dichloroethane
- 1,1-Dichloropropene
- 1,2-Dichloropropane
- 1,3-Dichloropropane
- 1,3-Dichloropropene
- 2,2-Dichloropropane

Ethylbenzene

Styrene

- 1,1,2-Trichloroethane
- 1,1,1,2-Tetrachloroethane
- 1,1,2,2-Tetrachloroethane

Tetrachloroethylene

1,2,3-Trichloropropane

Toluene

- p-Xylene
- o-Xylene
- m-Xylene

List 2: Required for Vulnerable Systems

Ethylene dibromide (EDB)

1,2-Dibromo-3-Chloropropane (DBCP)

List 3: Monitoring Required as the State's Discretion

Bromochloromethane

n-Butylbenzene

Dichlorodifluoromethane

Fluorotrichloromethane

Hexachlorobutadiene

Isopropylbenzene

p-Isopropyltoluene

Naphthalene

n-Propylbenzene

sec-Butylbenzene

tert-Butylbenzene

1,2,3-Trichlorobenzene

1,2,4-Trichlorobenzene

1,2,4-Trimethylbenzene

1,3,5-Trimethylbenzene

CLW 0000001628

The compounds in List 1 can be analyzed easily with the analytical methods in this final rule (Methods 502.1, 503.1, and 524.1). As previously discussed, the Agency has also developed capillary column methods (Methods 502.2 and 524.2) that are also available for the monitoring of these compounds. Monitoring for the compounds in List 2 (EDB and DBCP) requires much lower limits of detection and quantitation because of health concerns at low levels; as stated above, EPA Method 504 is available for the analysis of these two compounds at lower levels. Analysis of compounds in Lists 2 and 3 is best accomplished using the capillary column methods.

Analysis for unregulated contaminants must be conducted in laboratories approved for VOC analysis by the State. Because the monitoring requirements for unregulated contaminants will go into effect before full certification programs can be implemented, EPA will accept monitoring data analysis from those laboratories that analyze performance evaluation samples for VOCs within acceptable limits of the true value for the VOCs and that have been approved for THM analysis. The acceptance limits are \pm 0 percent for concentrations \pm 0.010 mg/l and \pm 0 percent for concentrations <0.010 mg/l. Laboratories conducting EDB and DBCP analysis should be approved separately by the State.

The monitoring requirements for the unregulated VOCs are similar to those required for the regulated VOCs so that public water systems are encouraged to use the same samples for all the analyses and to have the analysis of the unregulated VOCs performed with the analysis for the regulated VOCs, thereby reducing the costs of both sampling and analysis. This approach was generally supported by commenters.

The State would determine whether to require consecutive systems to monitor for VOCs and

trihalomethanes under Section 1445 for systems with a population of less than 10,000. If the consecutive system disinfects, then the samples for trihalomethanes should be taken after disinfection. This is because these systems currently do not monitor for trihalomethanes and trihalomethane concentrations usually increase after disinfection by the consecutive systems.

The November 1985 proposal did not include repeat monitoring for unregulated VOCs (unless imposed by the State). In this final rule, however, EPA is requiring repeat monitoring for unregulated contaminants every five years, as specified in the SDWA Amendments of 1986. However, EPA expects to specify a new list for unregulated contaminant monitoring within five years. This means that PWSs will not actually have to conduct repeat monitoring for the list of 50 specified in this notice, but instead will monitor for a new list in five years. However, States are encouraged to require follow-up monitoring for these 50 contaminants and mitigation procedures as needed if contamination is indicated.

States may delete contaminants from the list if EPA approves, and can add contaminants to the list for individual public water systems without EPA approval. The State may apply to EPA for approval in order to delete a substance for an individual water system by certifying to EPA that it has used the vulnerability criteria in reaching that decision. EPA will retain oversight authority of this process.

Section 1445(a)(6) states that EPA may waive the monitoring requirements for unregulated VOCs for systems that have conducted monitoring programs since January 1, 1983. EPA will waive this requirement only if the monitoring program was consistent with the requirements promulgated today. "Consistent" means the sampling locations, sampling techniques, and analytical methods are the same, and the analyses were performed by qualified laboratories (i.e., laboratories that are THM-certified) with adequate quality control. While EPA would prefer that all of the 33 VOCs on List 1 would have been included in the previous monitoring program, the Agency intends the requirements to be flexible so that systems that have monitored for most of the 33 VOCs could qualify for a waiver. For example, if 30 of 33 VOCs were included in a previous monitoring program by a particular system, that system might qualify for a waiver depending upon which three VOCs were not included. If these were relatively high occurrence VOCs, then a waiver would be inappropriate. Other factors that EPA will consider are the results of the monitoring program for the contaminants that were analyzed and the system's vulnerability status.

Under section 1445(a)(7), systems serving fewer than 150 connections are treated as complying with the unregulated contaminant monitoring requirements if the systems provide water samples or the opportunity for sampling. While EPA encourages these systems to request the additional analytical results for the unregulated contaminants from laboratories conducting their analysis for VOC compliance monitoring since the additional cost is relatively small (probably \$50 or less), this is not a requirement of this rule. Under the final rule, these systems are required to send a letter to the State specifying that their system is available for sampling; no samples are to be sent unless requested by the State.

States or the water systems may composite up to 5 samples when monitoring for unregulated contaminants. The compositing procedure is described in the section on Compliance Monitoring.

IV. Effective Dates

These regulations have an effective date of January 1, 1988: the laboratory performance requirements and monitoring for compliance requirements (§ 141.24(g)) and the unregulated monitoring and reporting requirements (§ 141.35 and 141.40) [Prior to the adoption of the compliance monitoring requirements by the State, the authority for compliance monitoring is section 1445 of the Act]. All other provisions promulgated in this final rulemaking (concerning MCLs, variance, and exemptions, provisions of reporting and recombleding) are effective January 9, 1989, as provided in section 1412(b)(10).

V. Impact Analyses

The economic impact analysis supporting this final rule is contained in "Economic Impact Analysis of Proposed Regulations to Control Volatile Synthetic Organic Chemicals in Drinking Water," October 1985, as amended (Ref. 3). The report presents estimates of the benefits and costs of regulatory alternatives. Also included are analyses required by the Regulatory Flexibility Act and the Paperwork Reduction Act. The purpose of the assessment was to determine overall economic impacts of the regulations. The addendum to the assessment responds to comments made during the public comment period. There has been no significant change in the initial assessment, which showed that approximately 1300 community water supplies would be expected to exceed the final standards without additional controls. If nearly all these systems took actions to comply with the regulations, the total present value cost of compliance to the nation would be about \$280 million. On an annualized basis, the cost of compliance would be \$21 million per year. Extending the VOC regulations to non-community non-transient water systems will require approximately 400 additional systems to treat their water, at a capital cost of \$20 million and approximately \$1.5 million per year.

The cost impacts on community water systems and consumers affected by volatile organic contamination vary depending upon the size of the PWS. Very small systems which serve from 25 to 500 people could be expected to increase their water rates by approximately 54 cents per 1000 gallons of water. As a result of economies of scale, large community systems serving more than 50,000 people could be expected to increase their rates only about 5 cents per 1000 gallons. These increases would only affect systems with contaminant levels above the standards.

Under Executive Order 12291, EPA must judge whether a regulation is "major" and, therefore, subject to the requirements of a Regulatory Impact Analysis. This action does not constitute a "major" regulatory action because it will not have a major financial or adverse impact on the country. This regulation has been reviewed by the Office of Management and Budget as required by Executive Order 12291 and their comments are available in the public docket.

The costs of compliance monitoring and monitoring for the unregulated contaminants are presented in Table 7 (see Ref. 3). As noted above, composites of up to five sources are allowed and the costs shown in Table 7 assume that systems composite a number of their sources. In addition, certain States conduct monitoring for small systems. Compositing of different system sources by States is allowed in the regulations; savings are estimated to be \$500,000 per year for the initial compliance monitoring, \$200,000 per year for the initial unregulated monitoring, and \$400,000 per year for the repeat compliance monitoring.

TABLE 7. -- COSTS (\$ MILLION/YEAR)
FOR MONITORING FOR COMPLIANCE
WITH MCLS FOR VOCS AND FOR
UNREGULATED VOCS

Initial Round:

VOCs subject to MCLs \$7.5
Unregulated contaminants \$1.7
Repeat Monitoring:
VOCs subject to MCLs \$19.2
Unregulated contaminants n1

n1 The cost for repeat monitoring of unregulated contaminants will vary because the Agency will specify a new list of contaminants to be monitored in five years. Consequently,

contaminants other than those specified in this notice may be listed at that time.

The Regulatory Flexibility Act requires EPA to explicitly consider the effect of regulations on small entities. If there is a significant effect on a substantial number of small systems, the Agency must seek means to minimize the effects. With respect to the requirements of the Regulatory Flexiblity Act, 5 U.S.C. 602 et seq., today's action will not have a significant effect on a substantial number of small entities. Using the Small Business Administration's definitions, a "small" water utility is one that serves fewer than 50,000 people. There are about 78,500 such systems. Of these, fewer than 1700 are likely to have contamination levels greater than the MCLs. Therefore, this rule will affect about that 2 percent of the "small" systems, which does not constitute a substantial number of small systems. However, it is possible that today's action will have a substantial impact on a few small systems if regulated VOCs are found at levels higher than the MCL. Therefore, the Agency has attempted to provide alternatives to the requirements whenever possible. Specifically, EPA allows compositing of samples. Small systems may choose to composite their samples and to share the analytical costs. Also, the Agency has allowed bottled water and point-of-use devices as conditions of receiving a variance or exemption, even though decentralized treatment is less than the Agency's longrange goal of centralized treatment (due to untreated taps and possible inhalation effects), to accommodate the needs of the smaller systems with limited resources. The Agency also has given states the discretion to reduce monitoring frequency in accordance with a system's findings of no VOCs and its vulnerability status. Consequently, small systems which do not have VOC contamination in their water supply and are not located in a vulnerable area may have to monitor only infrequently. In addition, very small systems are not required to sample for unregulated contaminants; they are only required to provide a sample or make the opportunity for sampling available to the State.

The information collection requirements in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reducation Act, 44 U.S.C. 3501 *et seq.* The information collection requirements are not effective until OMB approves them and a technical amendment to that effect is published in the Federal Register.

VI. References and Public Docket

The following references are referred to in this notice and are included in the Public Docket together with other correspondence and information. The Public Docket is available for viewing by appointment in Washington, D.C. by calling the telephone number at the beginning of this notice. All public comments received on the proposal are included in the Docket.

- (1) * U.S. Environmental Protection Agency, Criteria and Standards Division, Analytical Methods/Monitoring the VOCs in Drinking Water. June, 1987.
- (2) * U.S. Environmental Protection Agency, Criteria and Standards Division, Techologies and Costs for the Removal of Volatile Organic Chemicals from Potable Water Supplies. May, 1985.
- (3) * U.S. Environmental Protection Agency, Office of Program Development and Evaluation, Economic Impact Analysis of Proposed Regulations to Control Volatile Synthetic Organic Chemicals in Drinking Water. October, 1985, as amended 1987.
- (4) U.S. Environmental Protection Agency, Criteria and Standards Division, Symmetry of Comments and EPA Responses on the Proposed MCLs for the VOCs, Reproposed MCLG for para-Dichlorobenzene, and "Requirements for Unregulated Contaminants." (June 1987)
- (5) Peters, W., and Clark, S. Memo: Risks Associated With Air Emissions from Aeration of Drinking Water. To Robert G. Kellam, Program Analysis and Technology Section and Arthur H. Perler, Science and Technology Branch, Criteria and Standards Division, Office of Drinking

Water. Nov. 13, 1985.

- (6) * National Toxicology Program, Toxicology and Carcinogenesis Studies of 1,4-Dichlorobenzene in F344 Rats and B6C3F[1] Mice (Gavage Studies), final report, 1987 (Technical Report Series No. 319).
- (7) U.S. Environmental Protection Agency Ground Water Supply Survey January 1983.
- (8) U.S. Environmental Protection Agency, Criteria and Standards Division. Criteria Document for ortho-Dichlorobenzene, meta-Dichlorobenzene, and parap-Dichlorobenzene. (June 1987)

The starred (*) documents are available for a fee from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. The toll-free number is 703/487-4650. These documents are also available for review at the Drinking Water Supply Branch Office in EPA's Regional Offices.

List of Subjects in 40 CFR Parts 141 and 142

Chemicals, Reporting and record-keeping requirements, Water supply, Administrative practice and procedure.

Dated: June 19, 1987.

Lee M. Thomas,

Administrator, Environmental Protection Agency.

Therefore, 40 CFR Parts 141 and 142 are amended as follows:

PART 141 -- [AMENDED]

- 1. In Part 141:
- a. The authority citation for Part 141 continues to read as follows:

Authority: 42 U.S.C. 300g-1, 300g-3, 300j-4, 300g-6, and 300j-9.

b. In § 141.2, the existing paragraph designations are removed, the existing paragraphs are arranged in alphabetical order, and the following new definitions are added:

§ 141.2. Definitions.

* * *

"Best available technology" or "BAT" means the best technology, treatment techniques, or other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration). For the purposes of setting MCLs for synthetic organic chemicals, any BAT must be at least as effective as granular activated carbon.

* * *

* * *

"Non-transient non-community water system or "NTNCWS" means a public water system that is not a community water system and that regularly serves at least 25 of the same persons over 6 months per year.

"Point-of-entry treatment device" is a treatment device applied to the drinking water entering a house or building for the purpose of reducing contaminants in the drinking water distributed throughout the house or building.

"Point-of-use treatment device" is a treatment device applied to a single tap used for the purpose of reducing contaminants in drinking water at that one tap.

* * *

- c. A new paragraph (g) is added to § 141.24 to read as follows:
- § 141.24 Organic chemicals other than total trihalomethanes, sampling and analytical requirements.

* * *

- (g) Analysis of the contaminants listed in § 141.61(a) for purposes of determining compliance with the maximum contaminant levels shall be conducted as follows:
- (1) Ground-water systems shall sample at points of entry to the distribution system representative of each well. Sampling must be conducted at the same location or a more representative location each quarter. Ground-water systems must sample every three months for each entry point to the distribution system except as provided in paragraph (g)(8)(i) of this section.
- (2) Surface water systems shall sample at points in the distribution system representative of each source or at entry points to the distribution system after any application of treatment. Surface water systems must sample each source every three months except as provided in paragraph (g)(8)(ii) of this section. Sampling must be conducted at the same location or a more representative location each quarter.
- (3) If the system draws water from more than one source and sources are combined before distribution, the system must sample at an entry point to the distribution system during periods of normal operating conditions.
- (4) All community water systems and non-transient, non-community water systems serving more than 10,000 people shall analyze all distribution or entry-point samples, as appropriate, representing all source waters beginning no later than January 1, 1988. All community water systems and non-transient non-community water systems serving from 3,300 to 10,000 people shall analyze all distribution or entry-point samples, as required in this paragraph (g), representing source waters no later than January 1, 1989. All other community and non-transient, non-community water systems shall analyze distribution or entry-point samples, as required in this paragraph (g), representing all source waters beginning no later than January 1, 1991.
- (5) The State or EPA may require confirmation samples for positive or negative results. If a confirmation sample(s) is required by EPA or the State, then the sample result(s) should be averaged with the first sampling result and used for compliance determination in accordance with (g)(9) of this section. States have discretion to delete results of obvious sampling errors from this calculation.
- (6) Analysis for vinyl chloride is required only for ground water systems that have detected one or more of the following two-carbon organic compounds: Trichloroethylene, tetrachloroethylene, 1,2-dichloroethane, 1,1,1-trichloroethane, cis-1,2-dichloroethylene, trans-1,2-dichloroethylene, or 1,1-dichloroethylene. The analysis for vinyl chloride typequired at each distribution or entry point at which one or more of the two-carbon organic

compounds were found. If the first analysis does not detect vinyl chloride, the State may reduce the frequency of vinyl chloride monitoring to once every three years for that sample location or other sample locations which are more representative of the same source. Surface water systems may be required to analyze for vinyl chloride at the discretion of the State.

- (7) A State or individual public water systems may choose to composite up to five samples from one or more public water systems. Compositing of samples is to be done in the laboratory by the procedures listed below. Samples should be analyzed within fourteen days of collection. If any organic contaminant listed in § 141.61(a) VOC is detected in the original composite sample, a sample from each source that made up the composite sample must be reanalyzed individually within fourteen days from sampling. The sample for reanalysis cannot be the original sample but can be a duplicate sample. If duplicates of the original samples are not available, new samples must be taken from each source used in the original composite and analyzed for VOCs. Reanalysis must be accomplished within fourteen days of the second sample. To composite samples, the following procedure must be followed:
- (i) Compositing samples prior to GC analysis.
- (A) Add 5 ml or equal larger amounts of each sample (up to 5 samples are allowed) to a 25 ml glass syringe. Special precautions must be made to maintain zero headspace in the syringe.
- (B) The samples must be cooled at 4 deg. C during this step to minimize volatilization losses.
- (C) Mix well and draw out a 5-ml aliquot for analysis.
- (D) Follow sample introduction, purging, and desorption steps described in the method.
- (E) If less than five samples are used for compositing, a proportionately smaller syringe may be used.
- (ii) Compositing samples prior to GC/MS analysis.
- (A) Inject 5-ml or equal larger amounts of each aqueous sample (up to 5 samples are allowed) into a 25-ml purging device using the sample introduction technique described in the method.
- (B) The total volume of the sample in the purging device must be 25 ml.
- (C) Purge and desorb as described in the method.
- (8) The State may reduce the monitoring frequency specified in paragraphs (g) (1) and (2) of this section, as explained in this paragraph as follows:
- (i) The monitoring frequency for ground-water systems is as follows:
- (A) When VOCs are not detected in the first sample (or any subsequent samples that may be taken) and the system is not vulnerable as defined in paragraph (g)(8)(iv) of this section, monitoring must be repeated every 5 years.
- (B) When VOCs are not detected in the first sample (or any subsequent sample that may be taken) and the system is vulnerable as defined in paragraph (g)(8)(iv) of this section,
- (1) Monitoring must be repeated every 3 years for systems >500 connections.
- (2) Monitoring must be repeated every 5 years for system </=500 connections.W

- (C) If VOCs are detected in the first sample (or any subsequent sample that may be taken), regardless of vulnerability, monitoring must be repeated every 3 months, as required under paragraph (g)(1) of this section.
- (ii) The repeat monitoring frequency for surface water systems is as follows:
- (A) When VOCs are not detected in the first year of quarterly sampling (or any other subsequent sample that may be taken) and the system is not vulnerable as defined in paragraph g(8)(iv), monitoring is only required at state discretion.
- (B) When VOCs are not detected in the first year of quarterly sampling (or any other subsequent sample that may be taken) and the system is vulnerable as defined in paragraph (g)(8)(iv) of this section,
- (1) Monitoring must be repeated in three years (for systems >500 connections.)
- (2) Monitoring must be repeated every five years (for systems </=500 connections.)
- (C) When VOCs are detected in the first year of quarterly sampling (or any other subsequent sample that may be taken), regardless of vulnerability, monitoring must be repeated every 3 months, as required under paragraph (g)(2) of this section.
- (iii) States may reduce the frequency of monitoring to once per year for a ground-water system or surface water system detecting VOCs at levels consistently less than the MCL for three consecutive years.
- (iv) Vulnerability of each public water system shall be determined by the State based upon an assessment of the following factors:
- (A) Previous monitoring results.
- (B) Number of persons served by public water system.
- (C) Proximity of a smaller system to a larger system.
- (D) Proximity to commercial or industrial use, disposal, or storage of Volatile Synthetic Organic Chemicals.
- (E) Protection of the water source.
- (v) A system is deemed to be vulnerable for a period of three years after any positive measurement of one or more contaminants listed in either § 141.61(a) or § 141.40(e) except for trihalomethanes or other demonstrated disinfection by-products.
- (9) Compliance with § 141.61(a) shall be determined based on the results of running annual average of quarterly sampling for each sampling location. If one location's average is greater than the MCL, then the system shall be deemed to be out of compliance. If a public water system has a distribution system separable from other parts of the distribution system with no interconnections, only that part of the system that exceeds any MCL as specified in Section 141.61(a) will be deemed out of compliance. States may reduce the public notice requirement to that portion of the system which is out of compliance. If any one sample result would cause the annual average to be exceeded, then the system shall be deemed to be out of compliance immediately. For systems that only take one sample per location because no VOCs were detected, compliance shall be based on that one sample.
- (10) Analysis under this paragraph shall be conducted using the following EA Wethods or

their equivalent as approved by EPA. These methods are contained in "Methods for the Determination of Organic Compounds in Finished Drinking Water and Raw Source Water," September 1986, available from Environmental and Support Laboratory (EMSL), EPA, Cincinnati, OH 45268 or the State.

- (i) Method 502.1, "Volatile Halogenated Organic Chemicals in Water by Purge and Trap Gas Chromatography."
- (ii) Method 503.1, "Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography."
- (iii) Method 524.1, "Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography/Mass Spectrometry."
- (iv) Method 524.2, "Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography/Mass Spectrometry."
- (v) Method 502.2, "Volatile Organic Compounds in Water by Purge and Trap Capillary Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series."
- (11) Analysis under this section shall only be conducted by laboratories that have received conditional approval by EPA or the State according to the following conditions:
- (i) To receive conditional approval to conduct analyses for benzene, vinyl chloride, carbon tetrachloride, 1,2-dichloroethane, trichloroethylene, 1,1-dichloroethylene, 1,1,1-trichloroethane, and paradichlorobenzene the laboratory must:
- (A) analyze Performance Evaluation samples which include these substances provided by EPA Environmental Monitoring and Support Laboratory or equivalent samples provided by the State.
- (B) achieve the quantitative acceptance limits under paragraphs (g)(11)(i)(C) and (g)(11)(i) (D) of this section for at least six of the seven subject organic chemicals. States may allow fewer than six of the seven.
- (C) achieve quantitative results on the analyses performed under (g)(11)(i)(A) that are within +/-20 percent of the actual amount of the substances in the Performance Evaluation sample when the actual amount is greater than or equal to 0.010 mg/l.
- (D) achieve quantitative results on the analyses performed under (g)((11)(i)(A)) of this section that are within +/-40 percent of the actual amount of the substances in the Performance Evaluation sample when the active amount is less than 0.010 mg/l.
- (E) achieve a method detection limit of 0.0005 mg/l, according to the procedures in Appendix B of Part 136.
- (F) be currently approved by EPA or the State for the analyses of trihalomethanes under § 141.30.
- (ii) To receive conditional approval for vinyl chloride, the laboratory must:
- (A) Analyze Performance Evaluation samples provided by EPA Envionmental Monitoring and Support Laboratory or equivalent samples provided by the State.
- (B) Achieve quantitative results on the analyses performed under (g)(11)($\frac{1}{2}$) this section that are within +/-40 percent of the actual amount of vinyl chloride in the Performance Evaluation sample.

- (C) Achieve a method detection limit of 0.0005 mg/l, according to the procedures in Appendix B of Part 136.
- (D) Receive approval or be currently approved by EPA or the State under (g)(11)(i) of this section.
- (12) States have the authority to allow the use of monitoring data collected after January 1, 1983, for purposes of monitoring compliance. If the data is consistent with the other requirements in this paragraph, States may use that data to represent the initial monitoring if the system is determined by the State not to be vulnerable under the requirements of this section. In addition, the results of EPA's Ground Water Supply Survey can be used in a similar manner for systems supplied by a single well.
- (13) States may increase required monitoring where necessary to detect variations within the system.
- (14) The State has the authority to determine compliance or initiate enforcement action based upon analytical results and other information compiled by their sanctioned representatives and agencies.
- (15) A public water system supplying fewer than 150 service connections shall be treated as complying with the monitoring requirements if the owner or operator sends a letter to the State specifying that their system is available for sampling. No samples may be sent to the State unless so requested. This letter must be sent to the State no later than January 1, 1991.
- (16) States may exempt a public water system that obtains treated water from another public water system serving more than 10,000 persons from conducting compliance monitoring for the organic chemicals under § 141.61(a), provided that the system from which the water is obtained has conducted the analyses required under § 141.61(a).
- (17) Public water systems exempted by the State under (g)(16) and which disinfect are required to monitor under § 141.40.
- (18) Each approved laboratory must determine the method detection limit (MDL), as defined in Appendix B to Part 136, at which it is capable of detecting VOCs. The acceptable MDL is 0.0005 mg/l. This concentration is the detection level for purposes of paragraphs (g) (5), (6), (7), and (8) of this section.
- d. Section 141.32 is amended by revising the first phrase of paragraph (a) to read as follows:
- § 141.32 Public notification.

* * *

- (a) If a community water system or non-transient non-community water systems fails to comply with an applicable maximum contaminant level established in Subpart B or G, **
- e. A new § 141.35 is added to Subpart D to read as follows:
- § 141.35 Reporting and public notification for certain unregulated contaminants.
- (a) The requirements of this section only apply to the contaminants list in \$141.40.
- (b) The owner or operator of a community water system or non-transient, non-continuous

water system who is required to monitor under § 141.40 shall send a copy of the results of such monitoring within 30 days of receipt and any public notice under paragraph (d) of this section to the State.

- (c) The State, or the community water system or non-transient, non-community water system if the State has not adopted regulations equivalent to § 141.40, shall furnish the following information to the Administrator for each sample analyzed under § 141.40:
- (1) Results of all analytical methods, including negatives;
- (2) Name and address of the system that supplied the sample;
- (3) Contaminant(s);
- (4) Analytical method(s) used;
- (5) Date of sample;
- (6) Date of analysis.
- (d) The owner or operator shall notify persons served by the system of the availability of the results of sampling conducted under § 141.40 by including a notice in the first set of water bills issued by the system after the receipt of the results or written notice within three months. The notice shall identify a person and supply the telephone number to contact for information on the monitoring results.
- f. Section 141.40 is revised to read as follows:
- § 141.40 Special monitoring for organic chemicals.
- (a) All community and non-transient, non-community water systems shall monitor for the contaminants listed in paragraph (e) in this section by date specified in Table 1:

TABLE 1. -- MONITORING COMPLETION DATE BY SYSTEM SIZE

	Monitoring to	
	begin no later	
Number of persons served	than	
Over 10,000	Jan. 1, 1988	
3,300 to 10,000	Jan. 1, 1989.	

Less than 3,300 Jan. 1, 1991.

- (b) Surface water systems shall sample in the distribution system representative of each water source or at entry points to the distribution system. The minimum number of samples is one year of quarterly samples per water source.
- (c) Ground water systems shall sample at points of entry to the distribution system representative of each well. The minimum number of samples is one sample per entry point to the distribution system.
- (d) The State may require confirmation samples for positive or negative results.

- (1) Chloroform
- (2) Bromodichloromethane
- (3) Chlorodibromomethane
- (4) Bromoform
- (5) trans-1,2-Dichloroethylene
- (6) Chlorobenzene
- (7) m-Dichlorobenzene
- (8) Dichloromethane
- (9) cis-1,2-Dichloroethylene
- (10) o-Dichlorobenzene
- (11) Dibromomethane
- (12) 1,1-Dichloropropene
- (13) Tetrachloroethylene
- (14) Toluene
- (15) p-Xylene
- (16) o-Xylene
- (17) m-Xylene
- (18) 1,1-Dichloroethane
- (19) 1,2-Dichloropropane
- (20) 1,1,2,2-Tetrachloroethane
- (21) Ethylbenzene
- (22) 1,3-Dichloropropane
- (23) Styrene
- (24) Chloromethane
- (25) Bromomethane
- (26) 1,2,3-Trichloropropane
- (27) 1,1,1,2-Tetrachloroethane
- (28) Chloroethane
- (29) 1,1,2-Trichloroethane

- (30) 2,2-Dichloropropane
- (31) o-Chlorotoluene
- (32) p-Chlorotoluene
- (33) Bromobenzene
- (34) 1,3-Dichloropropene
- (35) Ethylene dibromide (EDB)
- (36) 1,2-Dibromo-3-chloropropane (DBCP)
- (f) Community water systems and non-transient non-community water systems must monitor for EDB and DBCP only if the State determines they are vulnerable to contamination by either or both of these substances. For the purpose of this paragraph, a vulnerable system is defined as a system which is potentially contaminated by EDB and DBCP, including surface water systems where these two compounds are applied, manufactured, stored, disposed of, or shipped upstream, and for ground-water systems in areas where the compounds are applied, manufactured, stored, disposed of, or shipped in the ground-water recharge basin, or for ground-water systems that are in proximity to underground storage tanks that contain leaded gasoline.
- (g) Analysis under this section shall be conducted using the recommended EPA methods as follows, or their equivalent as determined by EPA: 502.1, "Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography," 503.1, "Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography," 524.1, "Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography/Mass Spectrometry," 524.2, "Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography/Mass Spectrometry, or 502.2, "Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series." These methods are contained in "Methods for the Determination of Organic Compounds in Finished Drinking Water and Raw Source Water." September 1986, available from Environmental Monitoring and Support Laboratory (EMSL), EPA, Cincinnati, Ohio 45268. Analysis of 1,2-dibromo-3-chloropropane (DBCP) and 1,2dibromoethane (EDB) shall be conducted by Method 504, "Measurement of 1,2,-Dibromoethane (EDB) and 1,2-Dibromo-3-chloropropane (DBCP) in Drinking Water by Microextraction and Gas Chromatography," September 1986, available from EMSL, Cincinnati, Ohio 45268 or the State.
- (h) Analysis under this section shall only be conducted by laboratories approved under \S 141.24(g)(11). In addition to the requirements of \S 141.24(g)(11), each laboratory analyzing for EDB and DBCP must achieve a method detection limit for EDB and DBCP of 0.00002 mg/l, according to the procedures in Appendix B of Part 136.
- (i) Public water systems may use monitoring data collected any time after January 1, 1983 to meet the requirements for unregulated monitoring, provided that the monitoring program was consistent with the requirements of this section.
- (j) Monitoring for the following compounds is required at the discretion of the State:
- (1) 1,2,4-Trimethylbenzene

. .

(2) 1,2,4-Trichlorobenzene

- (3) 1,2,3-Trichlorobenzene
- (4) n-Propylbenzene
- (5) n-Butylbenzene
- (6) Naphthalene
- (7) Hexachlorobutadiene
- (8) 1,3,5-Trimethylbenzene
- (9) p-Isopropyltoluene
- (10) Isopropylbenzene
- (11) Tert-butylbenzene
- (12) Sec-butylbenzene
- (13) Fluorotrichloromethane
- (14) Dichlorodifluoromethane
- (15) Bromochloromethane
- (k) Instead of performing the monitoring required by this section, a community water system or non-transient, non-community water system serving fewer than 150 service connections may send a letter stating that its system is available for sampling.
- (I) All community and non-transient, non-community water systems shall repeat the monitoring required in § 141.40 no less frequently than every five years from the dates specified in § 141.40(a).
- g. Section 141.50 is amended by revising paragraph (b) to read as follows:
- § 141.50 Maximum contaminant level goals for organic contaminants.

* * *

(b) MCLGs for the following contaminants are as indicated:

		MCDG
Cont	aminant	in mg/l
(1)	1,1-Dichloroethylene	0.007
(2)	1,1,1-Trichloroethane	0.20
(3)	para-Dichlorobenzene	0.075

- h. Section 141.60 is revised to read as follows:
- § 141.60 Effective dates.
- (a) The effective date for § 141.61 is January 9, 1989.
- (b) The effective date for § 141.62(b)(2) is October 2, 1987.

- i. Section 141.61 is added as follows:
- § 141.61 Maximum contaminant levels for organic contaminants.
- (a) The following maximum contaminant levels for organic contaminants apply to community water systems and non-transient non-community water systems.

Maximum contaminant CAS No. Contaminant level in mg/l 71-43-2 Benzene 0.005 75-01-4 Vinyl chloride 0.002 56-23-5 Carbon tetrachloride 0.005 107-06-2 1,2-Dichloroethane 0.005 79-01-6 Trichloroethylene 0.005 75-35-4 1,1-Dichloroethylene 0.007 71-55-6 1,1,1-Trichloroethane 0.20 106-46-7 para-Dichlorobenzene 0.075

- (b) The Administrator, pursuant to section 1412 of the Act, hereby identifies the following as the best technology, treatment techniques, or other means generally available for achieving compliance with the maximum contaminant level for synthetic organic chemicals (§ 141.61 (a)): Central treatment using packed tower aeration; central treatment using granular activated carbon for all these chemicals except vinyl chloride.
- j. Part 141 is amended by adding a new Subpart J, consisting of \S 141.100 and \S 141.101, to read as follows. Subparts H and I are reserved.

Subpart J -- Use of Non-Centralized Treatment Devices

Sec.

- 141.100 Criteria and procedures for public water systems using point-of-entry devices.
- 141.101 Use of other non-centralized treatment devices.

Subpart J -- Use of Non-Centralized Treatment Devices

- § 141.100 Criteria and procedures for public water systems using point-of- entry devices.
- (a) Public water systems may use point-of-entry devices to comply with maximum contaminant levels only if they meet the requirements of this section.
- (b) It is the responsibility of the public water system to operate and maintain the point-ofentry treatment system.
- (c) The public water system must develop and obtain State approval for a monitoring plan before point-of-entry devices are installed for compliance. Under the plan approved by the State, point-of-entry devices must provide health protection equivalent to central water treatment. "Equivalent" means that the water would meet all Primary and Secondary Drinking Water Standards and would be of acceptable quality similar to water distributed by a well-operated central treatment plant. In addition to the VOCs, monitoring must include physical measurements and observations such as total flow treated and plant condition

of the treatment equipment.

- (d) Effective technology must be properly applied under a plan approved by the State and the microbiological safety of the water must be maintained.
- (1) The State must require adequate certification of performance, field testing, and, if not included in the certification process, a rigorous engineering design review of the point-of-entry devices.
- (2) The design and application of the point-of-entry devices must consider the tendency for increase in heterotrophic bacteria concentrations in water treated with activated carbon. It may be necessary to use frequent backwashing, post-contractor disinfection, and Heterotrophic Plate Count monitoring to ensure that the microbiological safety of the water is not compromised.
- (e) All consumers shall be protected. Every building connected to the system must have a point-of-entry device installed, maintained, and adequately monitored. The State must be assured that every building is subject to treatment and monitoring, and that the rights and responsibilities of the public water system customer convey with title upon sale of property.
- § 141.101 Use of other non-centralized treatment devices.

Public water systems shall not use bottled water or point-of-use devices to achieve compliance with an MCL. Bottled water or point-of-use devices may be used on a temporary basis to avoid an unreasonable risk to health.

PART 142 -- [AMENDED]

- 2. In Part 142:
- a. The authority citation for 40 CFR Part 142 continues to read as follows:

Authority: 42 U.S.C. 300g-2, 300g-3, 300g-4, 300g-5, 300j-4, and 300j-9.

- b. A new § 142.56 is added to Subpart F, to read as follows:
- § 142.56 Bottled water and point-of-use devices.
- (a) A State may require a public water system to use bottled water or point-of-use devices as a condition for granting an exemption from the requirements of § 141.61(a) of this part.
- (b) Public water systems that use bottled water as a condition of obtaining an exemption from the requirements of § 141.61(a) must meet the requirements set out in § 142.62(f) of this part.
- (c) Public water systems that use point-of-use devices as a condition for receiving an exemption must meet the requirements set out in § 142.62(g) of this part.
- c. A new § 142.62 is added to Subpart G to read as follows:
- § 142.62 Variances from the maximum contaminant levels for synthetic organic chemicals.
- (a) The Administrator, pursuant to section 1415(a)(1)(A) of the Act, hereby identifies the following as the best technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for synthetic organic chemicals: Removal using packed tower aeration; removal using granular activated carbon (except for vinyl chloride).

- (b) A State shall require community water systems and non-transient, non-community water systems to install and/or use any treatment method identified in § 141.62(a) as a condition for granting a variance except as provided in paragraph (c). If, after the system's installation of the treatment method, the system cannot meet the MCL, that system shall be eligible for a variance under the provisions of section 1415(a)(1)(A) of the Act.
- (c) If a system can demonstrate through comprehensive engineering assessments, which may include pilot plant studies, that the treatment methods identified in § 141.62(a) would only achieve a *de minimis* reduction in contaminants, the State may issue a schedule of compliance that requires the system being granted the variance to examine other treatment methods as a condition of obtaining the variance.
- (d) If the State determines that a treatment method identified in paragraph (c) of this section is technically feasible, the Administrator or primacy State may require the system to install and/or use that treatment method in connection with a compliance schedule issued under the provisions of section 1415(a)(1)(A) of the Act. The State's determination shall be based upon studies by the system and other relevant information.
- (e) The State may require a public water system to use bottled water or point-of-use devices or other means as a condition of granting a variance from the requirements of § 141.61(a), to avoid an unreasonable risk to health.
- (f) Public water systems that use bottled water as a condition for receiving a variance from the requirements of § 141.61(a) must meet the following requirements in either paragraph (f)(1) of (f)(2) of this section in addition to requirements in paragraph (f)(3) of this section:
- (1) The Administrator or primacy State must require and approve a monitoring program for bottled water. The public water system must develop and put in place a monitoring program that provides reasonable assurances that the bottled water meets all MCLs. The public water system must monitor a representative sample of the bottled water for all contaminants regulated under § 141.61(a) the first quarter that it supplies the bottled water to the public, and annually thereafter. Results of the monitoring program shall be provided to the State annually.
- (2) The public water system must receive a certification from the bottled water company that the bottled water supplied has been taken from an "approved source" as defined in 21 CFR 129.3(a); the bottled water company has conducted monitoring in accordance with 21 CFR 129.80(g) (1) through (3); and the bottled water does not exceed any MCLs or quality limits as set out in 21 CFR 103.35, 110, and 129. The public water system shall provide the certification to the State the first quarter after it supplies bottled water and annually thereafter.
- (3) The public water system is fully responsible for the provision of sufficient quantities of bottled water to every person supplied by the public water system, via door-to-door bottled water delivery.
- (g) Public water systems that use point-of-use devices as a condition for obtaining a variance from NPDWRs for volatile organic compounds must meet the following requirements;
- (1) It is the responsibility of the public water system to operate and maintain the point-ofuse treatment system.
- (2) The public water system must develop a monitoring plan and obtain State approval for the plan before point-of-use devices are installed for compliance. This monitoring plan must provide health protection equivalent to a monitoring plan for central water treatment.

- (3) Effective technology must be properly applied under a plan approved by the State and the microbiological safety of the water must be maintained.
- (4) The State must require adequate certification of performance, field testing, and, if not included in the certification process, a rigorous engineering design review of the point-of-use devices.
- (5) The design and application of the point-of-use devices must consider the tendency for increase in heterotrophic bacteria concentrations in water treated with activated carbon. It may be necessary to use frequent backwashing, post-contractor disinfection, and Heterotrophic Plate Count monitoring to ensure that the microbiological safety of the water is not compromised.
- (6) All consumers shall be protected. Every building connected to the system must have a point-of-use device installed, maintained, and adequately monitored. The State must be assured that every building is subject to treatment and monitoring, and that the rights and responsibilities of the public water system customer convey with title upon sale of property.

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